IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

THE WASHINGTON UNIVERSITY,) TGFCEVGF RWDNÆ XGTUKQP
Plaintiff,))
) C.A. No. 13- 2091 (GMS)
V.))
WISCONSIN ALUMNI RESEARCH FOUNDATION,)
Defendant.)
))
	ý)

WASHINGTON UNIVERSITY'S PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

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I. INTRODUCTION

Plaintiff The Washington University ("Washington University") is a top-tier teaching and research university located in St. Louis, Missouri. Dr. Eduardo Slatopolsky, a professor of renal medicine, has spent the last 50 years at Washington University conducting pioneering research into the pathophysiology of renal diseases, including chronic kidney failure.

In the mid-1990s, Dr. Slatopolsky collaborated with Dr. DeLuca, a professor of chemistry at the University of Madison-Wisconsin with expertise in Vitamin D chemistry, on medical research that would ultimately result in a life-saving breakthrough in treating chronic kidney failure. The breakthrough involved Dr. Slatopolsky and Dr. DeLuca's discovery of a novel and nonobvious method of administering a particular Vitamin D analog ("paricalcitol," later sold as "Zemplar" by WARF's longstanding licensing partner Abbott Laboratories¹) to treat a serious condition associated with chronic kidney disease known as renal osteodystrophy ("RO") while avoiding dangerous increases in blood phosphate levels known as "hyperphosphatemia." The discovery resulted in a patentable invention — the '815 patented treatment method — jointly conceived by Dr. Slatopolsky and Dr. DeLuca.

Shortly after the discovery, Defendant Wisconsin Alumni Research Foundation ("WARF"), the licensing branch of the University of Madison-Wisconsin, approached Washington University about a deal. The parties entered into a written contract — "the Inter-Institutional Agreement" or "IIA" — in November 1995. WARF agreed to take the lead as the "senior party" in patenting the technology, entering into license agreements with commercial partners on the parties' behalf, administering those licenses for the parties' "mutual benefit," and

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¹ Abbott Laboratories is currently known as AbbVie, Inc. Subject to a few exceptions (*e.g.*, when quoting from specific documents), these Proposed Findings of Fact and Conclusions of Law generally refers to both entities as "Abbott."

sharing any resulting licensing revenues with Washington University. WARF also promised to use "all reasonable efforts to cooperate" with Washington University regarding WARF's "licensing" activities. In exchange, Washington University agreed to refrain from commercializing or licensing the invention, to pay WARF an uncapped 15% administration fee "as consideration for securing and administering" any license agreements on the parties' behalf, and to receive only 33.3% any resulting licensing revenues (with WARF receiving 66.7% because Dr. DeLuca invented the particalcitol compound).

Unbeknown to Washington University, however, WARF either knew or would soon learn that the parties' jointly owned patent held tremendous value, but would deliberately mislead Washington University into believing that the patent was virtually worthless in order to deprive Washington University of its equitable share of the royalties attributable to the parties' patent.

By March 1998, WARF knew that the FDA had relied on Dr. Slatopolsky's '815 patent study as demonstrating Zemplar's advantages over an existing Abbott drug known as calcitriol (sold as Calcijex). In April 1998, the FDA approved Zemplar to treat a medical condition associated with chronic kidney disease known as secondary hyperparathyroidism ("SHPT"), and requested additional studies before approving Abbott's requested RO indication (which is recited in the '815 patent claims). As WARF's own tech transfer expert admitted at trial, Abbott decided not to pursue a formal RO indication *because Abbott knew physicians would prescribe Zemplar to treat both SHPT and RO* based on their close medical relationship. On June 12, 1998, a WARF Licensing Manager (Gayle Kirkpatrick), who was also a former Abbott employee and who had attended a Zemplar "training session" at Abbott only one month earlier with Dr. DeLuca and WARF's Managing Director Carl Gulbrandsen, wrote to Abbott that "[w]e recognize that [the '815 patented] technology directly supports" Zemplar. Despite WARF's

actual knowledge that the '815 patent "directly support[ed]" Zemplar, WARF did not disclose this highly relevant information to Washington University.

Effective July 28, 1998, WARF and Abbott entered into a new license agreement ("the 1998 Abbott License") that added the parties' co-owned '815 patent to a previously-licensed portfolio of Vitamin D patents solely owned by WARF. As WARF would repeatedly acknowledge to third parties over the ensuing 15 years (including to this very Court), but conceal from Washington University, the '815 patent substantially contributed to Zemplar's immense commercial success and to Abbott's exclusivity in the market, in particular because of the '815 patent's key teachings and claim limitations directed to "avoiding hyperphosphatemia." As WARF would also acknowledge to third parties and this Court, Abbott received *an exclusive license* to the '815 patent under the terms of the 1998 Abbott License, and paid *a 7% "earned royalty" obligation* for its use of that patent. The '815 patent was one of only three patents in the Abbott portfolio to generate such "earned royalties," along with WARF's '497 compound patent and '925 treatment method patent that also supported Zemplar. The '815 patent therefore contributed at least equally with WARF's '497 and '925 patents in generating the \$427.6 million in "earned royalties" that Abbott paid to WARF over their 18 year licensing relationship.

When it came time to share those \$427.6 million in royalties with Washington University under the parties' agreement, however, WARF not only actively concealed the '815 patent's true relative value from Washington University, but also engaged in self-dealing by exploiting a contractual provision it had drafted granting it "authority to assign relative values" to the parties' co-owned '815 patent and the WARF-owned patents bundled into the Abbott portfolio. Stepping far outside WARF's authority under that provision, WARF arbitrarily — and without performing any patent-specific evaluation of the '815 patent at all — allocated 99.032% of the Zemplar

royalty stream to WARF's wholly owned patents licensed to Abbott, the vast majority of which WARF now concedes had no connection to Zemplar. WARF allocated only 0.968% relative value to the parties' '815 patent, which WARF knew "directly support[ed]" Zemplar. In total, WARF paid itself \$426.5 million of Zemplar's licensing royalties, while remitting a little over \$1 million to Washington University under the IIA. Not surprisingly, WARF's Managing Director testified that WARF's "blended" valuation approach to the Abbott portfolio (which diluted the '815 patent's share with 29 valueless WARF patents) "worked beautifully" for WARF.

To justify this allocation to Washington University, WARF engaged in a pattern of deceit, untruths, and misdirection that concealed WARF's breach from Washington University. Washington University learned only in discovery that WARF had falsely represented in May 1998 that "confidentiality provisions" in WARF's license agreements with Abbott supposedly prevented WARF from sharing those agreements with Washington University. But as WARF's own tech transfer expert admitted at trial, the relevant Abbott license agreements contained no such "confidentiality provisions," and WARF's refusal to share them with Washington University prevented Washington University from evaluating WARF's assertions that the '815 patent was worth negligible value compared to WARF's solely-owned patents in the portfolio.

WARF candidly admits, as it must, that there is "some truth" to Washington University's allegations that Washington University "has been 'kept in the dark' all along." (D.I. 154-1, Ex. 12 at 6.) In WARF's April 4, 2001 letter to Washington University purporting to explain its relative valuation process, WARF represented that the '815 patent was "ancillary" to Zemplar and that "it [was] difficult if not impossible for WARF to determine whether or not the ['815] patent [was] being used by [Abbott] at this time," when in reality WARF knew that the '815 patent "directly support[ed]" Zemplar, and that WARF had *arbitrarily classified* the parties' '815

patent as "ancillary" without performing any patent-specific evaluation at all. As WARF's own tech transfer expert admitted, Washington University reasonably expected that WARF would use all known information about the value of the '815 patent when conducting a relative valuation. Washington University learned only in discovery that WARF had ignored all relevant valuation evidence when WARF assigned the parties' '815 patent a negligible 0.968% relative value.

WARF also misrepresented its valuation policies and practices to Washington University, claiming in its April 4, 2001 letter that WARF had assigned 70% relative value to WARF's "compound patents . . . in accordance with WARF's regular practice," when in reality WARF had only one "compound patent" (the '497 patent), which it had assigned 35% value. WARF allocated another 35% to WARF's solely-owned treatment method patent (the '925 patent) that, like the '815 patent, supported Zemplar, but had a shorter life than the '815 patent and did not contain the '815 patent's key teachings about avoiding hyperphosphatemia. WARF's misrepresentation created the false impression that WARF did not have a "regular practice" of assigning substantial value to treatment patents that supported Zemplar, like the '815 patent.

WARF further misrepresented in its April 4, 2001 letter that WARF had assigned the remaining 30% relative value to all remaining "Ancillary Patents" in the portfolio in equal shares in accordance with "WARF's policy to allocate evenly among these patents regardless of whether or not the patent is actually currently being used by the Licensee." In reality, WARF had no such "policy" — its actual policy, which WARF concealed from Washington University, granted WARF discretion to assign *any* patent, including the "ancillary" patents, substantial value based on its "disproportionate value . . . in the development and commercialization" of the licensed drug. Washington University learned of WARF's misrepresentations only from documents obtained in discovery, including from a relative valuation that WARF had performed

in 1997 in which WARF had assigned a disproportionate 29% relative value to a WARF-owned treatment method patent in the "ancillary" group in an analogous valuation context.

In this lawsuit, Washington University asserts claims for breach of contract and breach of the implied covenant of good faith and fair dealing in order to hold WARF accountable for its failure to assign a fair value to the '815 patent, for its self-dealing valuation conduct, for its concealment and misrepresentations, and for its annual underpayments to Washington University under the IIA's Annual Payment Clause. WARF's merits-based defenses fail because they conflict with WARF and Abbott's sworn testimony and evidence advanced in their 2012 litigations to block third-party companies from selling a generic form of Zemplar. And, as the Third Circuit presaged, WARF's statute of limitations defense poses no barrier to Washington University's recovery in this case.² Wisconsin's longstanding equitable estoppel doctrine bars WARF from asserting a statute of limitations defense in light of WARF's active concealment and misrepresentations, on which Washington University reasonably relied to its detriment.³

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² Washington University disputes WARF's assertion that the Third Circuit "remanded this Court's grant of summary judgment for resolution of a discrete subset of material factual issues it found in dispute." (D.I. 154-1, Ex. 12 at 3.) The Third Circuit's opinion and mandate contained no such limitation. The Third Circuit merely "reversed" this Court's prior summary judgment ruling *without stating* that it was remanding for resolution of any particular facts. The Third Circuit clarified that its identification of specific factual disputes in its opinion was "not intended as an exhaustive listing of the issues of material fact" and that it identified those issues "merely to illustrate that this record does not support summary judgment, and WARF was therefore not entitled to judgment as a matter of law." (D.I. 141-2 at 8 n. 22.) The Court's resolution of this case, therefore, does not depend on any purported "subset" of factual issues. *See Bankers Tr. Co. v. Bethlehem Steel Corp.*, 761 F.2d 943, 950 (3d Cir. 1985) ("A trial court is thereby free to make any order or direction in further progress of the case, not inconsistent with the decision of the appellate court, as to any question not settled by the decision.").

³ Equitable estoppel doctrine does not require intent to deceive, only "(1) action or non-action; (2) on the part of one against whom estoppel is asserted; (3) which induces reasonable reliance thereon by the other, either in action or non-action; (4) which is to the relying party's detriment." Wash. Univ. v. Wis. Alumni Research Found., 703 F. App'x 106, 109 (3d Cir. 2017) (citing Affordable Erecting, Inc. v. Neosho Trompler, Inc., 715 N.W.2d 620, 628 (Wis. 2006)).

Independently, Wisconsin's periodic payment doctrine allows Washington University to assert claims based on each of WARF's annual underpayments that occurred on or after April 9, 2007 (six years before the parties' Standstill Agreement). Because the IIA required WARF to make annual payments to Washington University, WARF breached the agreement each year it made annual payments in amounts less than those due under a fair relative valuation of the '815 patent, giving rise to a separate six-year statute of limitations period on each of WARF's annual underpayments. WARF's annual breaches were especially egregious given WARF's peculiar knowledge of the true relative value of the '815 patent, which it had concealed from Washington University, and in particular in years when it should have been even more obvious to WARF that its relative valuation of the '815 patent did not fairly compensate Washington University, such as in 2008 when a newly-hired WARF employee "rediscovered" that the '815 patent directly supported Zemplar. WARF's own tech transfer expert confirmed that WARF not only had a duty to assign a fair value to the '815 patent in the first place, but also had "a duty to revalue" in the event Washington University raised a challenge (which WARF's concealment and misrepresentations prevented) or when WARF later realized its initial valuation was incorrect.

Washington University seeks up to \$39.2 million in damages, plus an additional \$18.4 million in prejudgment interest, based on WARF's contractual breaches and other misconduct.

II. PROPOSED FINDINGS OF FACT

A. The Parties and Jurisdiction

- Washington University is a not-for-profit Missouri corporation having its
 principal place of business at One Brookings Drive, St. Louis, Missouri 63130. (D.I. 154-1, Ex.
 Uncontested Fact No. 1.)
- 2. Founded in the mid 1850's, Washington University now has over 3,400 faculty members and 13,000 full-time students in undergraduate and graduate programs, including

business, arts and sciences, law, and medicine. (Trial Tr. 395:15-396:3 (Mr. Surber).)
Washington University is also well-known for their number of Nobel Laureates: the Nobel Prize has been awarded to 23 laureates affiliated with Washington University. (*Id.*)

- 3. WARF is a not-for-profit Wisconsin corporation having its principal place of business at 614 Walnut Street, Madison, Wisconsin 53726. (D.I. 154-1, Ex. 1, Uncontested Fact No. 2.) WARF is the designated technology transfer organization for the University of Wisconsin-Madison. (*Id.*, Uncontested Fact No. 3.) WARF has approximately 2.7 billion dollars in assets. (Trial Tr. 727:16-21 (Mr. Gulbrandsen).)
 - 4. The amount in controversy exceeds \$75,000. (*Id.*, Uncontested Fact No. 4.)
 - B. Professors Dr. Slatopolsky from Washington University and Dr. DeLuca from the University of Wisconsin Jointly Invent a Method of Using Paricalcitol for Treating Renal Osteodystrophy While Avoiding Hyperphosphatemia
 - 1. Overview of the '815 Patented Invention and Its Inventors
- 5. Dr. Eduardo Slatopolsky is a professor of medicine and researcher in the renal division of the Washington University School of Medicine. (D.I. 154-1 Ex. 1, Uncontested Fact No. 5; Trial Tr. 118:7-119:9 (Dr. Slatopolsky).) Over the course of his 50-year career at Washington University, he has conducted pioneering research into kidney mineral metabolism, including studying the effect of calcium and phosphorous on cardiovascular disease stemming from kidney disease. (Trial Tr. 118:20-119:16 (Dr. Slatopolsky); Trial Tr. 396:9-21 (Mr. Surber); JX188.) Dr. Slatopolsky has published over 400 scientific manuscripts in his field of research. (Trial Tr. 396:22-397:2 (Mr. Surber).)
- 6. Dr. Slatopolsky is a named inventor on the parties' co-owned patent at issue in this lawsuit, entitled "Prevention of Hyperphosphatemia in Kidney Disorder Patients," U.S. Patent No. 5,597,815 ("the '815 patent")." (JX4 at 2.) The '815 patent is directed to a method

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of treating patients with renal osteodystrophy (a complication of chronic kidney disease) while avoiding hyperphosphatemia (dangerous increases in blood phosphorous levels) by administering a class of 19-nor Vitamin D2 analogs, including the drug compound "paricalcitol" that Abbott later sold under the brand name "Zemplar." (JX4 at 8 at claim 4; D.I. 154-1, Ex. 1, Uncontested Fact No. 29.)

7. Dr. Hector DeLuca, a prominent professor and researcher at the University of Wisconsin in the field of Vitamin D chemistry and medicine, is the other named inventor on the parties' co-owned '815 patent. (JX4 at 2; Trial Tr. 120:3-6 (Dr. DeLuca).) Dr. DeLuca performed pioneering work in the 1970s and 1980s at the University of Wisconsin studying Vitamin D metabolism and its mechanism of action. (Trial Tr. 639:1-641:9 (Mr. Gulbrandsen).)

2. Background to the '815 Patented Invention

- 8. Before Dr. Slatopolsky and Dr. DeLuca's joint invention, the leading drug compound used to treat patients with chronic kidney disease was a Vitamin D3 analog known as "calcitriol." (Trial Tr. 639:1-641:9 (Mr. Gulbrandsen); *see also* JX85, FOF ¶¶ 39-42.) Calcitriol had the ability to suppress parathyroid hormone (PTH), thereby treating conditions associated with chronic kidney disease such as secondary hyperparathyroidism ("SHPT") and renal osteodystrophy ("RO"). (JX85, FOF ¶¶ 16-17, 28; JX82 ¶¶ 37; JX83 ¶¶ 22-24, 50-51.) Dr. DeLuca first identified the chemical structure of calcitriol in the 1970s. (Trial Tr. 640:1-13 (Mr. Gulbrandsen); *see also* JX85, FOF ¶¶ 22, 39-40.) Abbott sold calcitriol under the brand name "Calcijex" also under a license granted by WARF to a portfolio of DeLuca patents. (*Id.* at 641:10-14 (Mr. Gulbrandsen); *see also* JX85, FOF ¶¶ 39-42.)
- 9. Calcijex's use and efficacy were limited in some kidney disease patients because Calcijex could lead to deleterious side effects known as "hypercalcemia" (excessive blood calcium levels) and "hyperphosphatemia" (excessive blood phosphate levels). (Trial Tr. 160:4-

- 14 (Dr. DeLuca); *see also* JX80 ¶ 35; JX82 ¶ 24; JX83 ¶¶ 59-61; JX85, FOF ¶ 41.)

 Hypercalcemia can result in seizures, rickets, arrhythmias, or heart failure, while hyperphosphatemia can cause mineral deposits to form in a patient's soft tissue, including cardiovascular organs, leading to serious illness or death. (*See* JX80 ¶ 35; JX82 ¶ 23; JX83 ¶¶ 11, 61; JX85, FOF ¶¶ 27, 32-33, 41.)
- 10. As the WARF-DeLuca patents covering Calcijex neared their end of life, Abbott approached Dr. DeLuca about developing a next generation drug that would "succeed in keeping this franchise of Abbott alive and treating patients." (Trial Tr. 641:15-641:23 (Mr. Gulbrandsen); *see also* JX85, FOF ¶¶ 53-54.) In collaboration with other scientists at the University of Wisconsin, Dr. DeLuca synthesized a class of 19-nor Vitamin D2 and D3 analogs for potential development into a drug. (Trial Tr. 641:24-642:12 (Mr. Gulbrandsen).)
- 11. Dr. DeLuca described and claimed that class of compounds in U.S. Patent No. 5,587,497 ("the '497 patent"). (Trial Tr. 642:22-643:16; *see also* JX85, FOF ¶ 43; JX3 at 7 at claims 2-12.) A divisional patent based on the identical specification, U.S. Patent No. 5,246,925 ("the '925 patent") (*see* Trial Tr. 874:10-16 (Mr. Lentz)), covered a method of using those compounds to treat hyperparathyroidism by suppressing parathyroid activity. (Trial Tr. 643:17-644:1 (Mr. Gulbrandsen); *see also* JX85, FOF ¶ 237; JX2 at 7.)
- 12. The '497 and '925 patents disclosed and claimed "many" compounds. (Trial Tr. 150:19-151:4, 153:8-18 (Dr. DeLuca).) However, the '497 and '925 patents did not teach which of the many different claimed 19-nor Vitamin D2 and D3 compounds described in those patents would treat hyperparathyroidism without causing dangerous increases in serum calcium or serum phosphorous. (*See generally* JX83 ¶¶ 82-104; JX85, FOF ¶ 246; *see also* D.I. 163-2, Ex. B at 120:4-120:16 (Dr. DeLuca).) Neither patent contained any biological data showing the effect of

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19-nor Vitamin D compounds on parathyroid hormone (PTH) suppression or blood phosphorous levels. (Trial Tr. 163:15-24 (Dr. DeLuca); Trial Tr. 876:24-877:15, 880:15-19 (Mr. Lentz); *see also* JX85, FOF ¶ 310-314, 431, 466.) Nor did either patent contain any biological data relating to 19-nor Vitamin D2 analogs, like paricalcitol. (Trial Tr. 879:8-14 (Mr. Lentz); *see also* JX85, FOF ¶ 238-240; JX83 ¶ 100; JX2; JX3.) Vitamin D2 and D3 analogs have different structures and different biological effects. (Trial Tr. 150:19-152:13, 153:8-18, 161:12-162:8 (Dr. DeLuca); *see also* JX83 ¶ 100, 176; JX85, FOF ¶ 19, 42, 320.) Knowledge of the biological effects of one analog would not necessarily have translated into knowledge of the biological effects of another, especially with respect to a compound's effect on a patient's serum phosphorous levels. (Trial Tr. 878:19-879:1 (Mr. Lentz); *see also* JX83 ¶ 100; JX85, FOF ¶ 42-43; Trial Tr. 227:16-228:21 (Dr. Cleare).)

3. Dr. Slatopolsky's and Dr. DeLuca's Joint Invention

- 13. In 1993, WARF and Abbott entered into a license agreement ("the 1993 Abbott License") in which Abbott agreed diligently to pursue development and commercialization of two licensed 19-nor Vitamin D compounds covered by the '497 patent: paricalcitol and another compound known as 1 alpha, 25 dihydroxy-19-nor-24,24-dihomo-cholecalciferol (the "24,24-dihomo compound"). (Trial Tr. 647:4-20 (Mr. Gulbrandsen); Trial Tr. 188:1-189:1 (Dr. Cleare); JX5 § 3(A) & Appendix D.)
- 14. As noted above, it was not yet known in 1993 which of the two licensed compounds would suppress PTH without elevating blood calcium levels. (Trial. Tr. 136:17-137:12 (Dr. Slatopolsky); Trial Tr. 154:5-155:13 (Dr. DeLuca); Trial. Tr. 188:1-189:1 (Dr. Cleare).) Answering that question was the first "Action" that Abbott needed to undertake under Abbott's "Development Plan" for Zemplar in Appendix F of the 1993 Abbott License. (JX5 at 26.) The Development Plan outlined a number of studies that Abbott needed to perform before

submitting a New Drug Application (NDA) for one of the licensed 19-nor Vitamin D compounds. (*Id.*) The very first "Action" item referred to animal research to be performed by Dr. Slatopolsky in 1993 on the two licensed compounds to "[e]valuate PTH suppression and calcemia in uremic rat model." (JX5 at 26.)

- Dr. Slatopolsky was an ideal choice to carry out the studies that Abbott needed in connection with its anticipated NDA. Dr. DeLuca described Dr. Slatopolsky as "a nephrologist with a fairly astute knowledge of biochemistry," who had lab capabilities that Dr. DeLuca did not have, including the ability to "study[] parathyroid glands in culture" and to conduct in an animal model for chronic kidney disease called "the 5/6 nephrectomy model." (Trial Tr. 149:10-150:3 (Dr. DeLuca).) Dr. DeLuca's laboratory at the time, by contrast, was not studying parathyroid glands in culture, did not have the antibodies needed to study PTH in the blood, and was not performing 5/6 nephrectomy model studies. (D.I. 163-2, Ex. B at 27:20-28:11, 56:9-22 (Dr. DeLuca).)
- 16. In 1993, Dr. Slatopolsky completed "pilot studies" of the two licensed Vitamin D compounds using *in vitro* parathyroid cell cultures and a small-scale *in vivo* animal model. (Trial Tr. 136:17-137:12, 141:18-143:2 (Dr. Slatopolsky).) As reflected in Abbott's 1993

 Development Report, which WARF received in February 1994, Dr. Slatopolsky determined that "neither of the two analogs induced hypercalcemia," but only one of them paricalcitol was effective in suppressing PTH. (JX86 at 4.) Dr. Slatopolsky described these tests as "preliminary studies" that he performed to select the best analog for use in "the full long demanding expensive study" that led to the '815 patent. (Trial Tr. 141:18-143:2 (Dr. Slatopolsky).)
- 17. Dr. Slatopolsky not Dr. DeLuca designed and carried out the '815 patent study at the Washington University School of Medicine. (Trial Tr. 120:3-122:10 (Dr.

Slatopolsky); Trial Tr. 148:14-18 (Dr. DeLuca); *see also* D.I. 163-2, Ex. B at 26:20-25, 32:11-33:7, 34:22-41:13 (Dr. DeLuca).) Dr. DeLuca's role was limited to supplying the compound, formulation, and dosage information for the compounds that Dr. Slatopolsky used in the '815 patent study. (Trial Tr. 122:11-20 (Dr. Slatopolsky); D.I. 163-2, Ex. B at 32:11-33:1 (Dr. DeLuca).)

- 18. Dr. Slatopolsky "dedicated an entire lab, entire budget, a year of work in one single comparative study between calcitriol and paricalcitol." (Trial Tr. 120:23-122:10, 142:24-143:2 (Dr. Slatopolsky); Trial Tr. 148:14-18 (Dr. DeLuca).) Dr. Slatopolsky paid for the study in part with Washington University's own research funds and in part with funds from Abbott. (D.I. 163-8, Ex. H at 30:9-31:2 (Dr. Slatopolsky).)
- 19. In designing the '815 patent study, Dr. Slatopolsky came up with the idea to study whether paricalcitol could be administered in uremic rats in a manner that could have minimal effect on serum phosphorous levels and thereby avoid hyperphosphatemia. (Trial Tr. 128:1-20 (Dr. Slatopolsky); Trial Tr. 155:14-156:7 (Dr. DeLuca).) Dr. DeLuca testified that "it would [have been] logical for Dr. Slatopolsky to insist on" testing paricalcitol's effect on blood phosphorous levels because "serum phosphorous is a major concern in dialysis patients and the control of it is very important." (Trial Tr. 155:14-156:7 (Dr. DeLuca).)
- 20. When the results came in, Dr. Slatopolsky realized that paricalcitol could be administered in a manner to minimize blood phosphorous levels and avoid hyperphosphatemia. (Trial Tr. 128:1-20 (Dr. Slatopolsky).) Dr. Slatopolsky was the first scientist to make this discovery. (*Id*; *see also* Trial Tr. 164:7-11 (Dr. DeLuca).) Dr. DeLuca described Dr. Slatopolsky's finding as "important" because "rising serum phosphorous is of concern to nephrologists" and "so it's important if you have a drug that doesn't raise serum phosphorous to

the same degree as previously used drugs." (Trial Tr. 157:24-158:4 (Dr. DeLuca).)

- 21. Dr. DeLuca took Dr. Slatopolsky's data to a WARF patent attorney and pursued patents on the parties' co-invention. (Trial Tr. 164:1-6 (Dr. DeLuca); *see also* D.I. 163-2, Ex. B at 115:1-14 (Dr. DeLuca).) Other than informing Dr. Slatopolsky about his co-inventorship role in the '815 patented invention, Dr. DeLuca did not involve Dr. Slatopolsky in any patenting discussions. (D.I. 163-2, Ex. B at 116:3-22 (Dr. DeLuca).)
- 22. WARF filed the '815 patent application on July 13, 1995 based on the results of Dr. Slatopolsky's study. (Trial Tr. 164:1-6 (Dr. DeLuca); JX324.) The claims as originally filed were directed to "a method of avoiding hyperphosphatemia while treating a patient having a kidney disorder comprising administering to said patient a compound that has minimal effect on serum phosphorous of said patient." (Trial Tr. 127:11-24 (Dr. Slatopolsky); D.I. 163-8, Ex. H at 78:5-21 (Dr. Slatopolsky); JX324 at 26.) WARF amended the application's claims during patent prosecution to replace "kidney disorder" with "renal osteodystrophy." (JX324 at 97.) In the PTO's Notice of Allowability, the PTO allowed the '815 patent claims after finding that the relevant prior art, including Dr. DeLuca's '925 patented treatment method for paricalcitol, did not "teach or suggest an effect on phosphorous levels and the clear use of 19-nor Vitamin D2 to treat renal osteodystrophy." (JX324 at 112; Trial Tr. 885:13-886:15 (Mr. Lentz).)
- 23. The '815 patent ultimately issued on January 28, 1997. (JX4 at 1.) Claim 4 of the '815 patent recites "[a] method of treating a patient having renal osteodystrophy while avoiding hyperphosphatemia comprising administering to said patient [paricalcitol] that has minimal effect on blood serum phosphorous of said patient" (JX4 at 7-8, claims 1 and 4.)
 - C. Washington University and WARF Agree to Share Revenue Resulting from the '815 Patented Invention
 - 24. Around the same time as the filing of the '815 patent application, WARF

approached Washington University about entering into an inter-institutional agreement to govern their relationship with respect to their joint invention. (JX39 at 1.) An inter-institutional agreement is a common type of agreement in the university technology transfer industry that frames how universities will work together to commercialize a joint invention. (Trial Tr. at 173:20-174:12 (Dr. Cleare); Trial Tr. 356:2-12 (Dr. Brandt).)

- 25. Howard Bremer of WARF (a lawyer) prepared the IIA. (JX39 at 1; D.I. 163-3, Ex. C at 18:24-25 (Mr. Gulbrandsen).) Dr. E.J. Brandt of Washington University (a non-lawyer) reviewed it, proposed a handful of minor revisions, and signed the agreement on behalf of Washington University. (JX40 at 1; JX41 at 1; JX170 at 1; JX171 at 1; JX1 at 8; D.I. 163-4, Ex. D at 95:5-96:4 (Dr. Brandt).)
- 26. Effective November 1, 1995, Washington University and WARF signed a written contract, entitled the "Inter-Institutional Agreement for Prevention of Hyperphosphatemia in Kidney Disorder Patients" (the "Inter-Institutional Agreement" or "the IIA"). (JX1 at 1.)
 - 1. The Terms of the Inter-Institutional Agreement, Including the Cooperation Clause and Mutual Benefit Clause
- 27. As the IIA evidences, the IIA's purpose was to facilitate commercialization of the parties' joint invention embodied in the '815 patent application while ensuring that both Washington University and WARF fairly shared the resulting revenue. (JX1 at 1 ("Whereas, WARF and [Washington University] wish to enter into this Agreement to establish a means . . . for sharing income derived from licensing of the Patent"); *see also* Trial Tr. 352:15-353:2 (Dr. Brandt).)
- 28. WARF took the lead as the "senior party" pursuant to a common practice in the university technology transfer industry in which one party the "senior party" agrees to take on larger responsibilities than the "junior party," such as responsibility for patenting and

commercializing the invention. (Trial Tr. 175:1-18 (Dr. Cleare); Trial Tr. 933:22-934:4, 981:9-14 (Dr. Severson).) The "senior party - junior party" relationship is characterized by a high degree of trust and collaboration, reflecting the public benefit function that universities play when commercializing inventions that result from federally funded research. (Trial Tr. 172:3-173:14, 175:19-177:2 (Dr. Cleare); Trial Tr. 982:8-12 (Dr. Severson); Trial Tr. 380:15-381:6, 382:10-383:6, 391:12-21 (Mr. Kratochvil); Trial Tr. 364:5-13 (Dr. Brandt); *see also* D.I. 163-4, Ex. D at 49:3-50:8 (Dr. Brandt).) Under the "senior party - junior party" framework, the senior party is expected to keep the junior party informed of key events and decisions relating to the parties' joint IP, and to cooperate with and treat the junior party fairly when making key decisions affecting the junior party's interests and their shared mission of commercializing their joint IP. (Trial Tr. 177:3-20, 178:12-179:19 (Dr. Cleare); Trial Tr. 353:19-355:7, 363:19-364:13 (Dr. Brandt); Trial Tr. 391:12-21 (Mr. Kratochvil) ("We are the junior party, we shouldn't be reaching out to the senior party to find information that should be provided to us."); *see also* Trial Tr. 990:16-20 (Dr. Severson).)

- 29. WARF, as the senior party, assumed the responsibility to act on behalf of both parties in order to: (1) "prepare, file, prosecute, and maintain" patent rights arising from the invention; (2) "negotiate, execute, administer, and enforce" any license agreements; and (3) "determine whether or not the parties hereto shall engage in and prosecute any legal actions" involving those patent rights. (JX1 §§ 2(A)(i), 2(B)(i), 9(A).) WARF had the "exclusive right" to engage in all three activities; it had "sole discretion" to make decisions relating to the first two—patent prosecution and licensing; and it had "exclusive control" of any legal actions on the patents. (JX1 §§ 2(A)(i), 2(B)(i).)
 - 30. In its role as the senior party, WARF also promised to act on behalf of and for the

benefit of Washington University under the IIA. (JX1 §§ 1(D), 2(A)(iii), 2(A)(iv), 2(B)(ii); *see also* Trial Tr. 180:6-181:1 (Dr. Cleare).) Under the "Mutual Benefit Clause," WARF agreed to enter into license agreements "on behalf of" the parties and administer all license agreements for the "mutual benefit of the parties." (JX1 §§ 1(D), 2(B)(ii).) Under the "Government Reporting Clause," WARF agreed to "comply with all reporting requirements" to government agencies "on behalf of" Washington University. (JX1 § 2(A)(iv); Trial Tr. 276:11-15 (Dr. Cleare); Trial Tr. 938:21-939:20 (Dr. Severson).) These provisions demonstrate WARF's formal commitment to act on behalf of Washington University's joint interests in the parties' co-owned '815 patent when exercising WARF's delegated powers and responsibilities under the IIA.

- The parties also promised to cooperate with one another regarding all aspects of their joint mission to commercialize the '815 patent and share in its resulting revenues. Under the "Cooperation Clause," WARF agreed to "use all reasonable efforts to cooperate" with Washington University with respect to such activities as "licensing" and "execution of assignments." (JX1 § 2(A)(iii); Trial Tr. 179:5-19 (Dr. Cleare); Trial Tr. 944:6-18 (Dr. Severson).) The Cooperation Clause demonstrated WARF's formal commitment to keep Washington University reasonably informed of key events affecting their shared mission of commercializing the parties' joint invention and equitably sharing any resulting licensing revenues. (Trial Tr. 179:5-180:5 (Dr. Cleare); Trial Tr. 363:1-364:13 (Dr. Brandt) ("universities aren't out to do a job on each other"); Trial Tr. 384:17-21 (Mr. Kratochvil) ("It was nobody's responsibility at WashU [in 2002] to contact WARF. WARF should have contacted us.").)
- 32. Washington University, as the junior party, retained its ownership interest in the '815 patent, but gave up its right to commercialize the '815 patented invention, license the '815 patent to others, or enforce the '815 patent in legal actions. (JX1 at 1, Preamble; *id.* §§ 2(B)(i),

9(A).)

- 33. Washington University also agreed to pay a 15% administration fee to WARF, to be taken off the top of any "Income" attributable to the '815 patent. The express purpose of the administration fee was to provide WARF "consideration for securing and administering" any license agreements relating to the parties' joint invention. (JX1 §§ 1(G), 2(B)(iv).) Over the course of the parties' dealings, Washington University paid nearly \$620,000 in administration fees to WARF pursuant to this provision. (Trial Tr. 317:19-21 (Dr. Cleare); JX476A at 1.)
- 34. Washington University also agreed to accept only a 33.3% share of the revenues from licensing the '815 patent (after deducting for patent expenses), with WARF to keep the remaining 66.7% share. (JX1 § 3(A)(i)(1).) WARF's Managing Director explained that the "one-third two-thirds split" in WARF's favor reflected the fact that Dr. DeLuca "is the compound owner, and it's his overall project." (D.I. 163-3, Ex. C at 62:14-63:4 (Mr. Gulbrandsen).)
- 35. Therefore, under the terms of the IIA, after paying the administration fee and deducting certain patent expenses, Washington University would receive no more than 28.33% of the revenues attributable to the '815 patent. (JX1 §§ 1(G), 2(B)(iv), 3(B), 3(A)(i)(1).) WARF would take the lion's share of any licensing revenue generated by the parties' joint invention in consideration of WARF's role as the senior party and owner of the compound.
- 36. Washington University owed no further duties to WARF under the IIA, other than cooperating with WARF with respect to patent prosecution, licensing, and assignment activities. (See JX1; Trial Tr. 934:5-9 (Dr. Severson).)
- 37. As WARF's own tech transfer expert acknowledged, under the "senior party junior party" framework, Washington University had a reasonable expectation that WARF would

treat Washington University fairly and in a collegial manner, and that WARF would not make decisions that would adversely prejudice Washington University's interests in the parties co-owned '815 patent. (Trial Tr. 945:16-23, 982:8-12, 983:15-18 (Dr. Severson); *see also* JX1 §§ 2(A)(iii) (Cooperation Clause), 2(B)(ii) (Mutual Benefit Clause); Trial Tr. 175:19-177:20, 178:12-181:24 (Dr. Cleare); Trial Tr. 353:19-355:7, 356:15-19, 361:20-362:6, 363:1-18, 363:19-364:13 (Dr. Brandt); Trial Tr. 391:12-21 (Mr. Kratochvil).)

- 38. WARF's tech transfer expert also acknowledged that Washington University, as the junior party, had no responsibility to be distrustful of, exercise oversight over, or otherwise police WARF's performance under the IIA. (Trial Tr. 1003:17-20 (Dr. Severson); *see also* Trial Tr. 229:22-230:23 (Dr. Cleare); Trial Tr. 384:17-21 (Mr. Kratochvil).) To the contrary, WARF had a duty to be fair and honest in its dealings with Washington University under the IIA, and to keep Washington University reasonably informed about WARF's licensing activities pursuant to WARF's promise to "use all reasonable efforts to cooperate" with Washington University regarding "licensing" activities. (Trial Tr. 982:8-12, 983:15-18 (Dr. Severson); Trial Tr. 178:12-181:6 (Dr. Cleare); JX1 §§ 2(A)(iii) (Cooperation Clause), 2(B)(ii) (Mutual Benefit Clause); *see also* Trial Tr. 384:17-21 (Mr. Kratochvil) ("It was nobody's responsibility at WashU [in 2002] to contact WARF. WARF should have contacted us.").)
- 39. Washington University therefore reasonably expected that WARF, as the senior party, would keep Washington University in the loop about decisions affecting Washington University's interests in the parties' co-owned patent, including information reflecting the value of the parties' joint invention to potential licensing partners. (Trial Tr. 175:19-176:5 (Dr. Cleare); Trial Tr. 353:19-355:7 (Dr. Brandt); Trial Tr. 381:20-382:9, 384:17-21, 391:12-21 (Mr. Kratochvil).) As Dr. Cleare explained, the Cooperation Clause would have reasonably

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communicated to Washington University that WARF would provide Washington University with a "reasonable level of information as to what's going on" with WARF's licensing efforts. (Trial Tr. 178:12-179:19 (Dr. Cleare); JX1 § 2(A)(iii).) Similarly, the Mutual Benefit Clause would have reasonably communicated to Washington University that WARF would "com[e] to fair decisions that do not adversely prejudice" Washington University's interests. (Trial Tr. 180:6-181:1 (Dr. Cleare); JX1 § 2(B)(ii).)

40. As discussed in detail in Paragraphs 66-97 below, unbeknown to Washington University at the time, WARF actively concealed from Washington University all relevant information about the value of the '815 patent to Zemplar in order to deprive Washington University of its equitable share of the \$427.6 million in royalties it received from Abbott.

2. The Relative Value Clause

- 41. As part of the IIA, WARF included a provision ("the Relative Value Clause") that allowed it to license the parties' co-owned '815 patent as part of a larger portfolio of WARF's own patents. (JX1 § 3(A)(iii); JX39 at 1.) In that circumstance, WARF had the "authority to assign relative values" to the '815 patent and the WARF-owned patents licensed with it.

 WARF's assignment of relative value to the '815 patent would ultimately determine the amount of revenues that Washington University would receive under the IIA. (JX1 § 3(A)(iii).)
 - 42. Specifically, the Relative Value Clause provides:

"In licensing [the '815 patent], WARF may include rights under other patents . . . to which WARF owns a part of or all right title and interest In such event **WARF shall have the authority to assign relative values to [the '815 patent] and other patent . . . rights as are included in any such license** and the portion of the gross receipts from royalties and other fees received by WARF under any such license, which shall be Income hereunder to be divided with [Washington University] as provided in Section 3A(i), shall be determined in accordance with such relative values assigned to [the '815 patent] in proportion to the total value represented by all patent rights . . . which are included within such license."

(JX1 § 3(A)(iii).)(emphasis added.)

- 43. The IIA did not give WARF discretion to assign anything less than a fair relative value to the parties' co-owned '815 patent in light of all the circumstances. This Court previously determined on summary judgment that the duty of good faith and fair dealing required WARF "to exercise its 'authority' to assign relative values fairly and in good faith" under the IIA. (D.I. 130 at 21.) WARF did not appeal this Court's summary judgment ruling, which now stands as the law of the case. *See Chlystek v. Kane*, 540 F.2d 171, 173 (3d Cir. 1976) ("[W]e are bound by the determination of the district court, which has not been appealed.").
- 44. WARF's own tech transfer expert, Dr. Severson, also admitted that WARF had a responsibility under the IIA to assign a fair relative value to the parties' co-owned patent. (Trial Tr. 982:4-7 (Dr. Severson).)⁴

In addition, the term "authority" expressly grants narrower rights to WARF than the term "sole discretion," which the parties used to refer to WARF's decision-making rights under the Inter-Institutional Agreement with respect to certain patent prosecution and licensing activities. This distinction reflects the parties' intent to draw narrower rights around WARF's exercise of its delegated powers under the Relative Value Clause. In situations where WARF's and Washington University's interests were aligned, such as when filing for patent rights, securing licenses, or enforcing patent rights, the parties agreed that WARF would have greater latitude ("sole discretion" or "sole and exclusive right") when making decisions. However, in the royalty apportionment context, when WARF's assignment of relative values might come at Washington University's expense, the parties' agreed that WARF would have narrower rights ("authority"). (Compare JX1 § 3(A)(iii), with JX1 §§ 2(A)(i), 2(B)(i), 9.)

⁴ WARF's duty to assign fair relative value in light of all the circumstances is also embodied in the language and structure of the IIA. The plain meaning of "value" is "relative worth, merit, or importance" as in the sentence "the value of a college education; the value of a queen in chess." (JX362.) It can also mean "monetary or material worth, as in commerce or trade" or "estimated or assigned worth; valuation." Inherent within this definition is an objective standard for determining "value." (*Id.*) The plain meaning of "relative" is "considered in relation to something else; comparative." (*Id.*) In the context of the Relative Value Clause, the term "relative" refers to the value of the '815 patent relative to the value of the other patents licensed with it. This meaning is confirmed by the Relative Value Clause itself, which provides that the "Income hereunder to be divided with [Washington University] . . . shall be determined in accordance with such relative value[] assigned to [the '815 patent] in proportion to the total value represented by all patent rights . . . included within such license." (JX1 § 3(A)(iii).) One cannot assign "value" to one patent "relative" to other patents unless one applies the same fair and objective valuation standard to all patents in the portfolio. (*Id.*)

- 45. The factors commonly used in the tech transfer industry to measure a patent's relative value as compared to other patents include (1) whether the patent covers the drug or an approved indication of the drug, (2) whether the patent is valid and would be infringed by the licensed product in the absence of a license, (3) the duration of the remaining patent term at the time of licensing, (4) whether the patent confers exclusivity over the licensed product, and (5) whether the patent has been exclusively or nonexclusive licensed. (Trial Tr. 183:8-184:21, 204:14-205:17 (Dr. Cleare); Trial Tr. 887:20-888:1, 890:3-891:19, 895:13-17 (Mr. Lentz); Trial Tr. 990:16-20, 997:5-9 (Dr. Severson); D.I. 163-9, Ex. I at 79:17-21 (Mr. Stoveken); Trial Tr. 353:23-355:7, 363:1-364:13 (Dr. Brandt); JX10 at 3; JX15 at 2.)
- 46. WARF's written valuation policy reflects the kind of patent-specific valuation approach that is commonly applied in the university tech transfer industry. (*See* JX10 at 3.) WARF's policy vests its Licensing Managers with discretion to assign unequal value percentages to patents in a licensed portfolio "to reflect the disproportionate value of the Patent Families in the development and commercialization of product(s) under the agreement." (JX10 at 4; Trial Tr. 998:4-13 (Dr. Severson).) Mark Stoveken, a WARF Licensing Manager, confirmed that when he analyzes patent claims from a business-licensing perspective, he looks to see whether

Finally, the Mutual Benefit and Cooperation Clauses further confirm that WARF's "authority" under the Relative Value Clause required WARF to value the licensed patents fairly. Under the Mutual Benefit Clause, WARF agreed to "administer all License Agreement(s) for the mutual benefit of the parties." This language expressly prohibited WARF from engaging in self-dealing by administering any licensing agreements in a manner that enriched WARF at the expense of Washington University, including by assigning more than fair value to WARF's wholly-owned patents at the expense of the parties' co-owned '815 patent. (JX1 § 2(B)(ii).) Similarly, under the Cooperation Clause, WARF agreed to "use all reasonable efforts to cooperate with [Washington University]" relating to a broad range of activities, including "licensing." (JX1 § 2(A)(iii).) Inherent in WARF's duty of cooperation is the requirement that WARF cooperate, inform, and communicate honestly with Washington University regarding such key events as WARF's assignment of relative value to the parties' co-owned patent. (JX1 § 2(A)(iii).)

the patent is "something a licensee would be interested in taking a license to for enablement of product development and commercialization." (D.I. 163-9, Ex. I at 79:17-21 (Mr. Stoveken).) Mr. Stoveken also testified that if WARF were to exercise its discretion under WARF's written policy to assign unequal percentages to some patents over others in a licensed portfolio, WARF would "do what's best for all parties involved." (D.I. 163-9, Ex. I at 87:7-15 (Mr. Stoveken).)

- 47. Some of WARF's historical valuation practices embody a patent-specific valuation approach — at least, when it favored WARF's interests to perform that kind of analysis. (See JX15 at 2, 14-15.) When WARF assigned relative values to a portfolio of patents subject to a 1997 licensing amendment between WARF and Abbott to "be used exclusively for royalty payments deriving from the Multiple Sclerosis field," WARF assigned 29% relative value to a WARF-owned "Ancillary Patent" that supported a multiple sclerosis indication that Abbott was pursuing at the time. (*Id.*) WARF's Multiple Sclerosis patent (U.S. Patent No. 5,716,946) recited a method of treating multiple sclerosis symptoms by administering a Vitamin D analog. (JX248 at 9.) WARF's tech transfer expert, Dr. Severson, admitted that WARF's assignment of 29% relative value to the Multiple Sclerosis patent, despite being classified as "Ancillary" under the relevant license amendment (JX7 at 5), was consistent with the discretion WARF grants its Licensing Managers under its written valuation policy to assign disproportionate value to any patent in a licensed portfolio to reflect its patent-specific contributions to the development and commercialization of the licensed drug. (Trial Tr. 996:17-998:13 (Dr. Severson).)
- 48. As WARF's own tech transfer expert acknowledged, it would have been highly unusual in the university tech transfer industry for a senior party with responsibility for assigning relative values to a portfolio of patents to ignore patent-specific valuation information relevant to

those patents. (Trial Tr. 983:7-14 (Dr. Severson); *see also* Trial Tr. 184:11-21 (Dr. Cleare).) Specifically, Dr. Severson admitted that "if one party had information about the value of a [patent], that there would be a reasonable expectation that that party would use that information when valuing that patent." (Trial Tr. 983:7-14 (Dr. Severson).)

- 49. Consistent with this common expectation that WARF would assign relative values in light of all known information, Washington University's lead negotiator Dr. Brandt testified that "[u]sually valuation of patents is done in a fair and equitable way relative to the strength of support a given patent is providing to the commercialization of the product," and that she understood WARF would exercise its "authority" to assign relative values within a licensed portfolio consistently with this common practice. (Trial Tr. 356:15-19 (Dr. Brandt); *see also id.* 352:15-357:10, 363:1-364:18 (Dr. Brandt).) Dr. Brandt's state of mind at the time she signed the IIA was consistent with the common industry practice for the senior party to apply fair and reasonable patent-specific valuation criteria when assigning relative values, and for the senior party to discuss its valuation process honestly and accurately with the junior party. (Trial Tr. 990:16-20 (Dr. Severson); Trial Tr. 184:11-21, 204:14-205:17 (Dr. Cleare); Trial Tr. 887:20-888:1, 891:1-14 (Mr. Lentz).)
- 50. The parties' pre-contractual negotiations are also consistent with Washington University's reasonable expectation that WARF would assign a fair relative value to the '815 patent in light of all known information bearing on that patent's value. As WARF's lead negotiator Mr. Bremer explained in his July 21, 1995 letter to Dr. Brandt, WARF needed the "flexibility required and allowed" under the Relative Value Clause because WARF had "encountered great reluctance on behalf of its licensees to identify which of the parties" included in a portfolio was "actually being used." (JX39 at 1.) Mr. Bremer's emphasis on preserving

"flexibility" under the Relative Value Clause reasonably communicated to Washington
University that WARF would not apply an *inflexible* formula that would *ignore information*actually known to WARF about the value of the parties' co-owned patent. (Trial Tr. 976:16980:22 (Dr. Severson); D.I. 163-4, Ex. D at 109:21-113:9 (Dr. Brandt).) As Dr. Severson
acknowledged, Mr. Bremer did not exclude the possibility that, if WARF obtained information
about the licensee's use of the '815 patent, WARF would use that information when assigning
relative values under the "flexible" Relative Value Clause. (Trial Tr. 980:10-22 (Dr. Severson)
(agreeing that "Mr. Bremer [didn't] write in this letter WARF [was] going to ignore information
about the licensee's actual use of patent[s] when assigning value").) To the contrary, Dr.
Severson admitted that Washington University had a reasonable expectation that WARF would
use all known information regarding the value of the parties' co-owned '815 patent when
exercising its "authority" to assigning relative values under the IIA. (Trial Tr. 184:11-21 (Dr.
Cleare); Trial Tr. 983:7-14, 1000:21-1001:18, 1009:2-4 (Dr. Severson).)

- 51. As discussed in Paragraph 97 below, unbeknown to Washington University at the time, WARF performed no patent-specific evaluation of the parties co-owned '815 patent at all before assigning it negligible 0.968% relative value.
- 52. In addition, consistent with the clear directive of the IIA's Mutual Benefit Clause, Dr. Severson acknowledged that Washington University had a reasonable expectation that whatever standard WARF used to assign relative values to WARF's solely-owned patents in a licensed portfolio, that WARF would apply the same standard when assigning relative value to parties' co-owned '815 patent. (Trial Tr. 983:7-14, 1000:21-1001:18, 1009:2-4 (Dr. Severson); see also Trial Tr. 184:11-21 (Dr. Cleare); Trial Tr. 356:15-19 (Dr. Brandt); Trial Tr. 380:15-381:6 (Mr. Kratochvil).) Specifically, Dr. Severson admitted that WARF had a "professional"

obligation to treat [Washington University] fairly," and that this obligation extended to "not adopting a more favorable standard when it serve[d] [WARF's] interests and a less favorable standard when it [could] be used adverse to [Washington University's] interests." (Trial Tr. 1000:21-1001:18, 1009:2-4 (Dr. Severson).)

53. As discussed in detail in Paragraphs 107-115 below, unbeknown to Washington University at the time, WARF applied a much more favorable standard when assigning relative value to WARF's solely-owned patents than the standard it applied to the parties' co-owned patent, including assigning between 29% to 35% value to treatment method patents, while falsely representing to Washington University that WARF only assigned substantial value to "compound patents" and that WARF had a "policy to allocate evenly among [all ancillary] patents regardless of whether or not the patent is actually currently being." (JX49 at 1.)

3. The Annual Payment Clause

- 54. Under the IIA, WARF also agreed to an "Annual Payment Clause," under which WARF would "pay [Washington University] its share of Net Revenue due under this Agreement every 12 months" near the end of each fiscal year. (JX1 § 5(B); *see also* Trial Tr. 1105:3-23 (Ms. Mulhern).)
- As WARF's own damages expert explained, the IIA required WARF to calculate and remit to Washington University each year the royalties it owed to Washington University under the IIA. (Trial Tr. 1105:3-23 (Ms. Mulhern).) Each year, WARF calculated the amounts to remit to Washington University by taking "the top line revenue from Abbott," "look[ing] at what relative value it has allocated to Washington University," and "us[ing] that as one of the inputs to the calculation." (Trial Tr. 1105:3-23 (Ms. Mulhern).) WARF breached the IIA each year it failed to make annual payments under a fair relative value of the '815 patent. (*See infra* ¶¶ 293-302.)

- Despite the existence of an Annual Payment Clause, WARF has argued that the IIA did not require WARF to revisit, reconsider, or recalculate the relative value of the '815 patent after its initial value allocation in 1998. This argument ignores that Wisconsin's periodic payment doctrine applies independently of any continuing duty to revalue the patents in the portfolio, as WARF breached the IIA each year it made annual underpayments to Washington University. (See infra ¶¶ 293-302.) In any event, WARF had a duty to revalue under the IIA, as WARF's tech transfer expert acknowledged at trial. (Trial Tr.1028:4-1029:4 (Dr. Severson); see also infra ¶¶ 304-315.)
- 57. First, WARF's argument ignores that WARF's initial value allocation to the '815 patent in 1998 was grossly deficient, especially in view of WARF's contemporaneous statements to Abbott about the '815 patent's importance to Zemplar. (JX42 at 1; JX47 at 1; see also Trial Tr.526:18-527:3, 527:22-529:6 (Mr. Thomas).) As WARF's tech transfer expert agreed, it is "a common practice in the university tech transfer industry for the party with authority to assign relative values to revisit its value assignment if a challenge is made by an interested stakeholder." (Trial Tr. 1028:22-1029:4 (Dr. Severson); see also Trial Tr. 327:10-328:15 (Dr. Cleare) (testifying to same common practice).) WARF clearly had an obligation to assign a fair relative value to the '815 patent, as established by this Court's prior summary judgment ruling. (D.I. 130 at 21.) Failing that, WARF had an obligation to be honest with Washington University about its undervaluation, rather than actively conceal evidence of the '815 patent's value and misleadingly explain away WARF's improper valuation through half-truths, deceit, and misdirection. (See supra ¶ 38.) If WARF had disclosed its undervaluation to Washington University from the beginning, in October 1998, or in response to Washington University's inquiry about WARF's relative valuation in its April 4, 2001 letter, Washington University could

have brought an appropriate challenge, as it did in 2012 after independently learning about WARF and Abbott's use of the '815 patent in litigation in this Court to block generic Zemplar (which undermined WARF's earlier claims that the '815 patent was "ancillary" to Zemplar and virtually meaningless). (*See infra* ¶¶ 166-168.)

- 58. Second, WARF ignores that it had a duty to correct its initial undervaluation, especially because its undervaluation should have been obvious to WARF. WARF's own expert admitted that WARF "had a duty to revalue" in order to "be fair to Washington University" in the event WARF premised its original valuation on a mistaken determination that the '815 patent did not cover the licensed product, and then later learned of its mistake. (Trial Tr. 1028:4-21 (Dr. Severson); see also Trial Tr. 318:21-320:10, 327:10-328:15 (Dr. Cleare).) In light of WARF's actual knowledge by at least June 12, 1998 that the '815 patent covered Zemplar's approved use because of the medical equivalence of the SHPT and RO indications (see infra ¶¶ 67-77), WARF knew its 0.968% relative value assignment to the '815 patent did not fairly compensate Washington University for its co-ownership interest in the patent. WARF therefore had an ongoing duty to disclose and correct its undervaluation. (Trial Tr. 1028:4-21 (Dr. Severson).) WARF also incorrectly assumes that the IIA gave it the right to ignore laterdeveloped evidence — including Mr. Stoveken's 2008 email (discussed in Paragraphs 143-147) — that showed once again that WARF's initial valuation was improper. (JX50 at 1; Trial Tr. 693:1-13 (Mr. Gulbrandsen).)
- 59. Finally, WARF ignores that it was common practice in the industry for the senior party to revisit its relative value assignments in light of significant events, such as FDA approval. FDA approval commonly triggers a revaluation of relative value assignments because, after approval, the licensed patents' contribution to the development or commercialization of the

FDA-approved drug becomes clearer. (Trial Tr. 185:7-19, 318:21-320:10 (Dr. Cleare).)

WARF's written valuation policy embodies this common practice, providing that

"allocations . . . made at the time the agreement is first executed by WARF . . . can be amended in accordance with this policy," including when "changes are made to WARF's commercial arrangement with the licensee." (JX10 at 3.)

D. Washington University Performs Its Obligations Under the Contract

- 60. It is undisputed that Washington University performed all its obligations under the IIA. (Trial Tr. 1003:21-24 (Dr. Severson); JX448 at 8.)
- 61. Washington University refrained from commercializing the '815 patent, licensing it to others, or asserting it in legal actions against others, as required by the IIA. (JX448 at 8.)
- 62. Washington University also paid an uncapped 15% administration fee to WARF as required by the IIA. Over the course of the parties' 20-year contractual relationship, Washington University paid WARF nearly \$620,000 in administration fees "as consideration for [WARF's activities in] securing and administering" license agreements relating to the '815 patent. (Trial Tr. 317:11-24 (Dr. Cleare); Trial Tr. 566:2-567:10 (Mr. Thomas); JX476A at 1.)
- 63. Washington University also paid for certain patent prosecution fees in the United States and foreign filing expenses under the IIA. All told, Washington University paid over \$117,000 in such expenses to WARF. (Trial Tr. 567:23-568:20 (Mr. Thomas); JX476A at 1.)
- 64. Finally, Washington University accepted only 33.3% of the share of royalties that WARF allocated to the parties' co-owned '815 patent under the parties' "two-thirds one-third" royalty sharing agreement, in recognition of Dr. DeLuca's contribution of the particalcitol compound (and hence WARF's ownership of the compound patent). (JX1 § 3(A)(i)(1); Trial Tr. 567:15-17 (Mr. Thomas); D.I. 163-3, Ex. C at 62:14-63:4 (Mr. Gulbrandsen).)
 - 65. In total, out of the \$426.5 million of Zemplar's licensing royalties that Abbott

paid to WARF under the 1998 Abbott License, WARF allocated \$4.1 million to the '815 patent, took nearly \$620,000 in administration fees off the top of that income, deducted over \$117,000 in patent expenses, took \$2.3 million of the remainder as WARF's two-thirds share, and remitted to Washington University only \$1,053,426 under the IIA. (Trial Tr. 566:6-569:2 (Mr. Thomas); JX476A at 1-2.)

E. WARF Actively Conceals the Value of the '815 Patented Invention from Washington University

- WARF first assigned relative values to the parties' co-owned '815 patent and WARF's solely-owned patents in the Abbott portfolio by at least October 1998. (JX12 at 11.) By that time, WARF had actual knowledge of the importance of the '815 patent to the development and commercialization of Zemplar, but actively concealed that information from Washington University, despite WARF's contractual promises to "use all reasonable efforts to cooperate" with Washington University and to "administer all License Agreement(s) for the mutual benefit of the parties," and despite Washington University's reasonable expectations as the junior party that WARF, as the senior party, would keep Washington University reasonably informed about WARF's efforts to license the parties' patent in furtherance of their shared mission to commercialize their invention and equitably share in any resulting royalties. (*See generally* Trial Tr. 172:3-204:13 (Dr. Cleare); Trial Tr. 985:24-986:23, 988:16-989:5, 989:12-22, 991:24-992:5, 993:15-23, 998:14-999:3 (Dr. Severson); Trial Tr. 351:3-352:14 (Dr. Brandt); JX1 §§ 2(A)(iii) (Cooperation Clause), 2(B)(ii) (Mutual Benefit Clause).)
 - 1. WARF Knew Dr. Slatopolsky's '815 Patent Study Represented a Gating Item to Abbott's Development of Zemplar Under Abbott's "Development Plan" in the 1993 Abbott License
- 67. As set forth above, Dr. Slatopolsky's research beginning in 1993 and culminating in the '815 patent study demonstrated that paricalcitol could be administered in a way that would

treat renal osteodystrophy while avoiding hyperphosphatemia. (*See supra* ¶¶ 13-23.) WARF's 1993 license agreement with Abbott placed this research in the context of Abbott's development of Zemplar, showing that Abbott needed Dr. Slatopolsky's research study as the first "Action" item in Abbott's Development Plan for submitting an NDA on one of the two licensed 19-nor Vitamin D compounds under that license. (Trial Tr. 186:14-187:24 (Dr. Cleare).)

- 68. Even though the Cooperation Clause required WARF to use "all reasonable efforts to cooperate" with Washington University regarding WARF's "licensing" of the '815 patent to any third party, and despite Washington University's reasonable expectations that WARF would keep it reasonably informed about the value of the '815 patent, WARF did not share a copy of the 1993 Abbott License with Washington University. (JX1 § 2(A)(iii); Trial Tr. 178:12-180:5 (Dr. Cleare); Trial Tr. 371:11-372:7 (Dr. Brandt); Trial Tr. 389:6-11 (Mr. Kratochvil).) To the contrary, as discussed below (*see infra* ¶ 79-80), when Washington University later asked WARF for a copy of "any license and/or amendment that has either been executed or has the potential of being executed in the near future" (JX46 at 1), WARF refused citing "confidentiality provisions" that WARF's own tech transfer expert admitted did not exist.
- 69. Because Washington University only obtained a copy of the 1993 Abbott License through civil discovery in this lawsuit, Washington University's tech transfer office did not know that WARF and Abbott were already working to secure FDA approval of a 19-nor Vitamin D analog for use in patients with chronic kidney disease, and that the parties' '815 patented treatment method would play a major role in that process. (Trial Tr. 187:17-24 (Dr. Cleare); Trial Tr. 371:11-21 (Dr. Brandt); Trial Tr. 389:6-11 (Mr. Kratochvil).)
 - 2. WARF Knew the '815 Patent Application's Claims Provided "Additional Protection" to Zemplar
 - 70. In September 1996, a few months after the PTO allowed the claims of the '815

patent, a WARF Licensing Manager (Kenneth Johnson) with responsibility for the DeLuca patent portfolio wrote a letter to Abbott's General Manager (Loreen Mershimer) highlighting the value of the '815 patent to Zemplar. Mr. Johnson had a chemical engineering background and worked closely with Dr. DeLuca. (Trial Tr. 728:5-19 (Mr. Gulbrandsen).) In his letter, Mr. Johnson told Abbott that "I believe [the '815 patent] will provide additional protection for Abbott with [Zemplar] on the marketplace." (JX42 at 1; Trial Tr. 728:5-19 (Mr. Gulbrandsen).) Mr. Johnson also noted that WARF would share any resulting royalties it received from Abbott on the '815 patent with Washington University and Dr. Slatopolsky. (JX42 at 1.)

- 71. Because Mr. Johnson's letter bore directly on the importance and value of the '815 patent to Zemplar, WARF had an obligation under the Cooperation Clause and relevant professional standards in the university tech transfer industry to share that information with Washington University. (JX1 § 2(A)(iii); Trial Tr. 189:22-190:9 (Dr. Cleare).) Despite WARF's obligations and Washington University's reasonable expectations, WARF did not share Mr. Johnson's letter with Washington University or otherwise inform Washington University that the issued claims of the '815 patent application would provide "additional protection" for Zemplar. (Trial Tr. 190:10-14 (Dr. Cleare); Trial Tr. 985:24-986:6 (Dr. Severson).)
- 72. Because Washington University obtained a copy of Mr. Johnson's 1996 letter only through civil discovery in this lawsuit, Washington University's tech transfer office did not know that WARF had determined, after analyzing the issued patent's claims, that the '815 patent would protect Abbott's commercial sale of Zemplar. (Trial Tr. 189:7-21 (Dr. Cleare).)
 - 3. WARF Knew That the '815 Patent Study Helped Convince the FDA of the Advantages of Zemplar Over Calcijex
- 73. In January 1997, Abbott submitted a New Drug Application (NDA) for Zemplar ("the Zemplar NDA"). (D.I. 154-1, Ex. 1, Uncontested Fact No. 28.) In March 1998, the FDA

issued a written report of its medical review of Zemplar. (JX52 at 1.) WARF maintained a copy of the FDA's medical review in its files. (*See id.*) Under a section entitled, "Pharmacology Studies in Relation to Proposed Therapeutic Indication," the FDA cited Dr. Slatopolsky's '815 patent study (along with a follow-up study by Dr. Slatopolsky) as demonstrating not only the safety and efficacy of Zemplar, but also the advantages of Zemplar over Calcijex, including Zemplar's ability to suppress PTH as well as or better than Calcijex without causing an "increase in serum phosphorous." (JX52 at 6-7; *see also* Trial Tr. 190:23-193:6 (Dr. Cleare).)

- 74. WARF, as the senior party who agreed to "use all reasonable efforts to cooperate" with Washington University regarding its "licensing" activities, had a contractual and professional obligation to "keep [Washington University] in the loop" about the advantages of the '815 patent to the development and commercialization of Zemplar. (JX1 § 2(A)(iii); Trial Tr. 193:7-14 (Dr. Cleare).) Despite WARF's obligation and Washington University's reasonable expectations, WARF did not inform Washington University of the '815 patent study's role in helping Abbott convince the FDA of Zemplar's advantages over Calcijex and obtain FDA approval of Zemplar. (Trial Tr. 193:15-19 (Dr. Cleare).) Washington University obtained a copy of the FDA's medical review of Zemplar only during civil discovery in this lawsuit. (*Id.*)
 - 4. WARF Knew the '815 Patent Claims "Directly Support[ed]" the FDA's Approved Use of Zemplar
- 75. In April 1998, the FDA approved Abbott's NDA for Zemplar. (JX51 at 1.) Abbott launched Zemplar in May 1998. (Trial Tr. 716:6-8 (Mr. Gulbrandsen); JX207 at 1.) According to litigation papers that WARF and Abbott filed under seal in this Court in their 2012 lawsuit to block Hospira from selling generic Zemplar in violation of the '815 patent, Abbott had originally proposed that the FDA approve Zemplar for "the prevention and treatment of renal osteodystrophy and secondary hyperparathyroidism encountered with chronic renal failure."

(JX85, FOF ¶ 69.) After a teleconference with the FDA in March 1998, Abbott agreed to delete the words "renal osteodystrophy" — i.e., the indication recited in the '815 patent — from Zemplar's proposed label. (Id.) According to WARF and Abbott's litigation papers in the Hospira lawsuit, Abbott decided not to submit additional studies requested by the FDA to obtain a "renal osteodystrophy" indication on Zemplar's label "because (1) even without such data, treating physicians recognized the beneficial effect of reducing elevated parathyroid hormone levels in treating renal osteodystrophy because secondary hyperparathyroidism is encompassed by the broad term; and (2) [Abbott] did not want to delay approval of Zemplar in order to conduct such studies." (JX85, FOF ¶ 71.) Thus, Abbott recognized that even without the FDA's formal approval of an RO indication on Zemplar's label, "[t]he FDA-approved label for Zemplar demonstrates that Zemplar is safe and effective for the treatment of renal osteodystrophy while avoiding hyperphosphatemia as claimed in the '815 patent." (JX85, FOF ¶ 72.) When confronted with these papers at trial, WARF's tech transfer expert, Dr. Severson, admitted that they showed that "Abbott decided not to pursue the renal osteodystrophy indication at the time because it knew treating physicians would recognize that they could use Zemplar to treat RO" i.e., the indication directly recited in the '815 patent. (Trial Tr. 1027:4-9 (Dr. Severson) (emphasis added).)

76. On June 12, 1998, two months after FDA approval, a WARF Licensing Manager (Gayle Kirkpatrick) who took over responsibility for the DeLuca patent portfolio wrote a letter to Abbott's General Manager (Loreen Mershimer) highlighting once again the fact that the '815 patent "directly support[ed]" Zemplar. (JX47 at 1.) WARF's Managing Director explained the context in which Ms. Kirkpatrick wrote her June 12, 1998 letter to Abbott. (See Trial Tr. 712:1-717:3 (Mr. Gulbrandsen).) Ms. Kirkpatrick had come to WARF from Abbott. (Trial Tr. 712:14-

16 (Mr. Gulbrandsen).) After she arrived at WARF, she undertook a diligent and careful review of the Vitamin D patent portfolio, including the '815 patent, searching for patents to include in Abbott's license agreement for paricalcitol. (Trial Tr. 712:17-22, 715:7-11 (Mr. Gulbrandsen).) Shortly before Ms. Kirkpatrick wrote her June 12, 1998 letter to Abbott, Mr. Kirkpatrick had just attended a launch presentation and "training session" given by Abbott about Zemplar, which Dr. DeLuca and WARF's Managing Director, Mr. Gulbrandsen, had also attended. (Trial Tr. 715:21-24, 716:1-5 (Mr. Gulbrandsen); JX207 at 1.) Despite the FDA's rejection of an RO indication for Zemplar just a few months earlier, Ms. Kirkpatrick nevertheless confirmed her understanding that "[w]e recognize this technology directly supports the Abbott Zemplar™ product." (JX47 at 1 (emphasis added).) Ms. Kirkpatrick also acknowledged to Abbott that Dr. Slatopolsky would be entitled to a portion of the royalties that Abbott paid to WARF for Zemplar by virtue of the '815 patent's inclusion in the license. (JX47 at 1.)

- Zemplar to treat RO while avoiding hyperphosphatemia, as recited in the '815 patent claims, and that WARF's Ms. Kirkpatrick confirmed for Abbott that WARF understood the '815 patent "directly support[ed]" Zemplar, WARF did not share this information with Washington University, despite WARF's contractual and professional obligations, and the information's obvious importance to the parties' shared mission to license the '815 patent and equitably share in the resulting royalties. (*See* Trial Tr. 986:17-23 (Dr. Severson); Trial Tr. 198:12-199:6 (Dr. Cleare); JX1 § 2(A)(iii).) Washington University received a copy of WARF's June 12, 1998 letter for the first time during civil discovery in this lawsuit. (Trial Tr. 199:2-6 (Dr. Cleare).)
 - 5. WARF Knew the '815 Patent Would Generate 7% "Earned Royalties" Under the 1998 Abbott License
 - 78. Effective July 28, 1998 shortly after Ms. Kirkpatrick's letter to Abbott that the

'815 patent "directly supports" Zemplar (JX47 at 1) — WARF and Abbott entered into a new license agreement ("the 1998 Abbott License") that "supersede[d] the 1993 [Abbott License] with respect to [paricalcitol/Zemplar]," and that added the '815 patent to the bundle of IP rights licensed by Abbott in 1993. (D.I. 154-1, Ex. 1, Uncontested Fact Nos. 30-31.)

- 79. On May 13, 1998, just a couple months earlier, Washington University had asked WARF to see "any license and/or amendment that has either been executed or has the potential of being executed in the near future" between WARF and Abbott relating to the '815 patent. (JX46 at 1.) WARF responded that it had "an existing license agreement that, if the licensee agrees, will be amended to add" the '815 patent. (*Id.*) However, WARF refused Washington University's request to see a copy of all existing or pending license agreements, representing that, "per confidentiality *provisions*, I am not at liberty to provide you copies of our license agreements with any other parties." (*Id.* (emphasis added).)
- 80. Washington University learned only through discovery that WARF had falsely asserted that the relevant Abbott license agreements contained "confidentiality provisions" that prevented Washington University from seeing them. (Trial Tr. 194:20-195:18 (Dr. Cleare).)

 None of the relevant Abbott license agreements including the 1993 Abbott Agreement, two amendments to the 1993 Agreement executed in 1996, a proposed amendment on June 12, 1998 to add the '815 patent to the license agreement, and the 1998 Abbott Agreement contained any "confidentiality provisions" that would have prevented WARF from sharing those agreements with Washington University. (JX5-JX9; Trial Tr. 988:21-989:5 (Dr. Severson); Trial Tr. 194:20-195:18 (Dr. Cleare).) WARF's own tech transfer expert, Dr. Severson, admitted that he looked at the relevant license agreements to determine whether they had confidentiality provisions in them, but found none. (Trial Tr. 988:21-989:5 (Dr. Severson).) Importantly, Dr.

Severson also admitted that "Washington University had no reason at this time to think WARF wasn't being straightforward with them" when WARF refused Washington University's request to obtain a copy of the relevant Abbott Licenses based on non-existent "confidentiality provisions." (Trial Tr. 990:6-10 (Dr. Severson).)

- 81. The 1998 Abbott License contained a number of important pieces of information, without which Washington University could not evaluate WARF's later assertions in its April 4, 2001 letter about the relative value of the '815 patent compared to the other patents in the portfolio. (*See infra* ¶¶ 127-137.)
- 82. First, as Dr. Severson acknowledged, the 1998 Abbott License contained "a list of ancillary patents to which the '815 was bundled up together." (Trial Tr. 989:6-11 (Dr. Severson).) Dr. Severson admitted that Washington University needed that list to know whether WARF had assigned a fair relative value to the '815 patent. Specifically, Dr. Severson agreed that "without knowing the identities of the patents included in the 1998 Abbott License, Washington University couldn't determine or evaluate whether WARF had assigned a fair relative value to the '815 patent in proportion to the other patents in the portfolio." (Trial Tr. 989:12-22 (Dr. Severson).) Washington University obtained a copy of the 1998 Abbott License only in civil discovery in this lawsuit. (Trial Tr. 371:11-372:7 (Dr. Brandt); Trial Tr. 389:6-11 (Mr. Kratochvil).) The 1998 Abbott License divided the Abbott portfolio patents into two groups. The "Licensed Patents" in Appendix B contained two patents that were solely owned by WARF: the '497 patent that covered the paricalcitol compound and the '925 patent that covered a method of using paricalcitol to treat SHPT (but which contained no disclosure or claim limitations about how to avoid hyperphosphatemia). The "Ancillary Patents" in Appendix C contained the parties' co-owned '815 patent (JX8 at 24), bundled together with 29 Ancillary

Patents that were solely owned by WARF. (JX8 at 13-26.) The identities of the WARF-owned Ancillary Patents bundled with the '815 patent — and, importantly, their effect in diluting WARF's relative value allocation to the '815 patent — are discussed in Paragraphs 107-112 below.

- 83. Second, the 1998 Abbott License also revealed the conditions under which certain patents would give rise to "earned royalties" *i.e.*, an obligation by Abbott to pay WARF royalties based on Zemplar's sales. (JX8 at 4.) These conditions contradicted WARF's misleading statements in its April 4, 2001 that all ancillary patents lack substantial value, and that WARF purportedly had a "policy" of assigning them equal value "regardless of whether or not the patent is actually currently being used by the Licensee." (*See infra* ¶ 134-135.) The 1998 Abbott License provided that Abbott would pay "earned royalties" to WARF "whenever manufacture, use or sale of the Compound or Products, absent this license, would amount to an infringement of any claim of Licensed Patents or Ancillary Patents " (JX8 at 3.) Abbott agreed to pay a 7% royalty for any *exclusively* licensed patents, and a 5% royalty for any *nonexclusively* licensed patents, subject to an overall 7% royalty cap. (*Id.*) As discovery revealed to Washington University in this lawsuit, Abbott paid 7% earned royalties on the '815 patent (1) would have been infringed by Zemplar but for a license and (2) Abbott was the exclusive licensee of that patent. (*See, e.g.*, JX466 at 4.)
- 84. In the *Hospira* litigation, WARF and Abbott confirmed that the '815 patent (1) covered the approved use of Zemplar and that claim 4 of the '815 patent would be infringed by generic Zemplar sold in accordance with its FDA-approved label (JX63 at 6-10; JX85, FOF ¶ 181-236), and (2) was exclusively licensed to Abbott under the terms of the 1998 Abbott License and triggered a 7% "earned royalty" obligation. (JX85, FOF ¶ 1; JX426 at 105:7-17,

106:9-107:4, 109:6-14, 113:23-114:3 (Mr. Stoveken Rule 30(b)(6) testimony).)

- 85. WARF's Rule 30(b)(6) witness in the *Hospira* litigation (Mr. Stoveken) explained that, although it was not immediately apparent from the face of the 1998 Abbott License, the '815 patent was definitely licensed on exclusive terms to Abbott under that agreement. He explained that the '815 patent did not fall within the Exclusive License provision because the '815 patent was not a "Licensed Patent" listed in Appendix B. (JX426 at 102:2-14 (Mr. Stoveken Rule 30(b)(6) testimony); see JX8 at 1.) But the '815 patent did not fall within the Nonexclusive License provision either, however, because that provision related only to "Processes of Ancillary Patents and Licensed Patents," and the '815 patent "[was] not a process patent." (JX426 at 103:14-104:4 (Mr. Stoveken Rule 30(b)(6) testimony); see JX8 at 1.) Although the '815 patent seemed to fall outside the literal scope of both the Exclusive License and Nonexclusive License provisions, Mr. Stoveken — speaking for WARF — reconciled the apparent problem by explaining that WARF had licensed all method of treatment patents, like the '815 patent, to Abbott on exclusive terms, because the ancillary treatment patents "[were] distinct cases compared to the rest of the ancillary patents" that cover "Processes." (JX426 at 105:7-21 (Mr. Stoveken Rule 30(b)(6) testimony).) Mr. Stoveken unequivocally affirmed in the Hospira litigation that "it's plaintiff's position that WARF has granted Abbott an exclusive license to ancillary patents that relate to methods of treatment that you identified on pages 82[0]5 to 8207." (JX426 at 109:6-14 (Mr. Stoveken Rule 30(b)(6) testimony) (emphasis added).)
- 86. WARF's refusal to provide Washington University with a copy of the 1998

 Abbott License based on non-existent "confidentiality provisions" violated WARF's contractual and professional obligations to "duty to be honest to Washington University under the IIA," "use

all reasonable efforts to cooperate" with Washington University with respect to "licensing" activities, and to keep Washington University reasonably informed about matters affecting Washington University's interests in the parties' co-owned patent. (JX1 § 2(A)(iii); Trial Tr. 983:15-18 (Dr. Severson); Trial Tr. 178:12-181:6 (Dr. Cleare).) WARF's concealment of the relevant Abbott license agreements from Washington University also represented a significant departure from Washington University's reasonable expectations as the junior party to the IIA, as numerous witnesses familiar with customary tech transfer practices explained. (Trial Tr. 983:15-18 (Dr. Severson); Trial Tr. 194:20-195:18 (Dr. Cleare); Trial Tr. 371:11-372:7 (Dr. Brandt); Trial Tr. 380:15-381:6, 389:6-11 (Mr. Kratochvil).) Without access to the 1998 Abbott License, which Washington University obtained only in civil discovery, Washington University did not know that WARF had included its own '925 patented treatment method that covered Zemplar in the 70% "Licensed Patents" group for purposes of valuation (see infra ¶¶ 129-131) and had improperly diluted the '815 patent's relative value with 29 irrelevant patents owned solely by WARF (see infra ¶¶ 107-112). Washington University also did not know that Ancillary Patents, to which WARF had assigned the '815 patent for valuation purposes, had the potential to generated "earned royalties" and thus substantially contribute to Zemplar's royalty stream. (See infra ¶¶ 102, 113, 127, 153.)

6. WARF Knew the '815 Patent Substantially Contributed to Zemplar's Commercial Success

- 87. After Abbott launched Zemplar in May 1998, Zemplar enjoyed remarkable commercial success, which WARF and Abbott knew to be attributable in large part to the benefits and advantages of the '815 patented treatment method. (*See generally* JX84.)
- 88. Since Zemplar's launch in 1998, Zemplar has generated approximately \$6.1 billion in total sales revenues for Abbott. (JX85, FOF ¶ 82-85; JX476A at 1.) Sales of Zemplar

in the United States grew rapidly from about \$58 million in 1999, its first full year on the market, to its peak of about \$501.1 million in 2009, representing a compound annual growth rate of about 23.9 percent. (JX85, FOF ¶ 82.)

- 89. In 2001, Dr. DeLuca drafted a letter at Abbott's request to "put down my reasons why I think Zemplar should be used for treatment of these patients." (Trial Tr. 159:5-12 (Dr. DeLuca; JX87.) WARF did not share a copy of this letter with Washington University's technology transfer office, despite WARF's contractual and professional obligations and the letter's relevance to understanding the advantages of the '815 patent study to Zemplar's commercial success. (Trial Tr. 541:18-22 (Mr. Thomas); JX1 § 2(A)(iii).) Washington University obtained a copy of Dr. DeLuca's 2001 letter only during civil discovery in this lawsuit. (JX87.)
- 90. In his letter, Dr. DeLuca highlighted the health benefits of using Zemplar over Calcijex, and specifically cited Dr. Slatopolsky's '815 patent study as demonstrating that Zemplar represented "a major improvement" over Calcijex. (Trial Tr. 159:13-16 (Dr. DeLuca); Trial Tr. 539:19-541:17 (Mr. Thomas); JX87 at 1.) In particular, Dr. DeLuca pointed out that Zemplar "has the important characteristic of being almost equal to Calcijex in suppressing the parathyroid hormone, while having a much less dangerous profile in terms of raising blood calcium and phosphorous." (JX87 at 1; Trial Tr. 160:4-161:11 (Dr. DeLuca).) The '815 patent claims exactly that a way to administer Zemplar to suppress PTH while avoiding dangerous levels of blood phosphorous. (JX4 at 7.) As Dr. DeLuca pointed out in his letter, "[t]he design of Zemplar was proven very clearly by Dr. Slatopolsky who tested its activity in a model, namely the 5/6 nephrectomized rat. These animal experiments demonstrated a major improvement over Calcijex in terms of being effective with much less danger." (JX87 at 1.)

- 91. In connection with the *Hospira* litigation, WARF retained Dr. Vigil, an expert from the Analysis Group, to provide expert analysis and testimony regarding the commercial success of the '815 patented treatment method. Dr. Vigil signed his report on July 1, 2013. (JX84.) Through a careful analysis of Abbott's historical marketing documents and the factors that drove Zemplar's success in the marketplace, and especially among physicians, Dr. Vigil showed that Zemplar's success "has been due, in large part, to the benefits, merits, and advantages of the inventions described in the asserted claims of the '815." (JX84 ¶ 3.)
- 92. First, when analyzing Zemplar's commercial success, Dr. Vigil concluded that Zemplar was enormously successful as compared to its predecessor Calcijex. Citing third-party analyst reports, such as a March 1999 report by SG Cowen, Dr. Vigil found that Zemplar was "a real hit" that "command[ed] a 30% price premium to Calcijex." (JX84 ¶ 22.) According to Dr. Vigil's analysis, within six years after Zemplar's launch, Zemplar displaced virtually all of Calcijex's sales in the Renal Care market: "In 1998, the year that Zemplar IV launched, Abbott generated \$144 million in sales from its Renal Care products, 5 percent of which were generated from sales of Zemplar IV and 95 percent from sales of Calcijex IV. By 2004, sales of Zemplar IV accounted for approximately 99 percent of Abbott's \$388 million in total sales from its Renal Care products while Calcijex IV accounted for only 1 percent of total sales." (JX84 ¶ 50.)
- 93. Second, when analyzing the relationship between Zemplar's commercial success and the benefits, merits, and advantages of the '815 patented treatment method (*i.e.*, treating RO while avoiding hyperphosphatemia), Dr. Vigil found a direct correlation between the two. (JX84 ¶¶ 10, 31-40.) Dr. Vigil analyzed Abbott's marketing and promotional literature for Zemplar, and determined that one of the crucial selling points for physicians turned on the '815 patent's claimed teaching of avoiding hyperphosphatemia. (JX84 ¶¶ 31-40.) For example, Abbott's "Be

Selective" marketing campaign promoted Zemplar's ability to suppress PTH while having a "minimal effect on phosphorous and calcium levels." (JX84 ¶ 33.) Additional Abbott marketing documents similarly emphasized Zemplar's "[e]fficacy in treatment of hyperphosphatemic patients," and that Zemplar's ability to "reduce PTH levels with minimal absorption of Ca and P" may "increase survival and reduce risk of morbidities." (JX84 ¶¶ 35-36.)

- 94. At trial, WARF's technical expert, Mr. Lentz, agreed that what the PTO found nonobviousness about the '815 patented method namely, its method of using paricalcitol to treat RO while minimizing blood phosphorous levels and thus avoiding hyperphosphatemia was "the same effect that Dr. Vigil was getting at in his commercial success analysis." (Trial Tr. 885:22-886:6 (Mr. Lentz).)
- third-party subpoena from Hospira alerting Washington University to WARF and Abbott's assertion of the '815 patent in litigation, and Washington University and WARF were engaged in pre-litigation discussions regarding the appropriateness of WARF's relative value assignment to the '815 patent. (See infra ¶¶ 169-173.) WARF did not share Dr. Vigil's conclusions in the Hospira litigation with Washington University, despite their relevance to understanding the value of the '815 patent. (Trial Tr. 228:22-229:21 (Dr. Cleare).) To the contrary, WARF sent Washington University a letter in February 2013 only five months before Dr. Vigil signed his commercial success report asserting that all method of treatment patents, like the '815 patent, "are meaningless and largely irrelevant" next to WARF's patents (JX197 at 1.) Dr. Vigil's analysis of the '815 patent's importance to Zemplar's commercial success above and beyond the teachings in WARF's patents (see JX84 ¶¶ 51-52), contradicted WARF's assertions about the '815 patent's negligible value at another point in time when Washington University was trying to

obtain honest and accurate information about WARF's relative valuation under the IIA.

- F. WARF Characterizes the '815 Patent as "Ancillary," Does So Without Performing Any Patent-Specific Evaluation of the '815 Patent, Ignores Its Own Conclusion That the '815 Patent "Directly Supports" Zemplar, and Assigns the '815 Patent Negligible Relative Value
- o-owned patent; the others were solely owned by WARF. (JX8 at 12-26; JX2-4; JX209-256.) Under the IIA, WARF had "authority to assign relative values" to the '815 patent and the other patents licensed with it. For the reasons explained above, this provision required WARF to assign a fair value to the '815 patent, and to do so fairly. (JX1 § 3(A)(iii); *see also supra* ¶¶ 43-44.) Washington University therefore reasonably expected that WARF would use any information it had about the value of the parties' co-owned '815 patent when allocating relative value to that patent on Washington University's behalf, and that WARF would not engage in self-dealing by overallocating value to WARF's patents at the expense of the '815 patent. (*See* JX1 §§ 3(A)(iii) (Relative Value Clause), 2(B)(ii) (Mutual Benefit Clause); Trial Tr. 983:7-14, 1000:21-1001:18, 1009:2-4 (Dr. Severson); Trial Tr. 887:20-888:1, 891:1-14 (Mr. Lentz); Trial Tr. 179:5-180:5, 180:15-181:1, 183:8-184:21, 204:14-205:17 (Dr. Cleare); Trial Tr. 353:5-355:7, 361:20-362:6, 363:1-118, 363:19-364:13 (Dr. Brandt).)
- 97. Contrary to WARF's obligations under the IIA, WARF did not perform *any* patent-specific evaluation when assigning value to the parties' co-owned '815 patent relative to the WARF-owned patents licensed with it. (Trial Tr. 663:16-20 (Mr. Gulbrandsen); Trial Tr. 204:14-206:21 (Dr. Cleare); D.I. 163-3, Ex. C at 118:12-20 (Mr. Gulbrandsen Rule 30(b)(6)).) Instead, WARF arbitrarily assigned 70% value to the WARF-owned "Licensed Patents" in Appendix B (WARF's '497 and '925 patents). WARF then arbitrarily assigned the remaining 30% value to the "Ancillary Patents" in Appendix C (the co-owned '815 patent and about 30

WARF-owned patents). WARF then arbitrarily divided the 30% value equally among the about 30 "Ancillary Patents" as if each of those patents in fact had the same "relative value." (*See* Trial Tr. 674:17-675:3 (Mr. Gulbrandsen); Trial Tr. 200:13-201:22, 205:18-206:21 (Dr. Cleare); Trial Tr. 548:7-23 (Mr. Thomas); JX12 at 11.) WARF's arbitrary scheme for assigning relative value resulted in a 0.968% allocation to the '815 patent, and 99.032% allocation to the WARF-owned patents. (Trial Tr. 548:7-23 (Mr. Thomas); JX49 at 2.) After accounting for the parties' agreement to share royalties 66.7% to WARF and 33.3% to Washington University, less the uncapped 1% administration fee and allowable patent expenses, Washington University received only about 0.32% share of the total Zemplar royalty stream under the 1998 Abbott License. (Trial Tr. 564:19-569:2 (Mr. Thomas); JX476A.)

- 98. As explained in detail below, there was no economic justification for WARF to have assigned such a low relative value to the '815 patent in October 1998, when WARF first assigned a 0.968% relative value to the parties' '815 patent. (*See generally* Trial Tr. 527:22-546:15 (Mr. Thomas); JX12 at 15-16.) Nor was there any economic justification for WARF to have assigned the exact same relative value to each of the other so-called "Ancillary Patents," the vast majority of which did not read on Zemplar or the approved use of Zemplar, as it did for the '815. (*See generally* Trial Tr. 231:10-239:2 (Dr. Cleare); Trial Tr. 548:7-550:7 (Mr. Thomas).)
- 99. WARF knew at the time it performed its relative valuation that the '815 patent was one of the most important patents in the Abbott portfolio, as demonstrated by its repeated statements to Abbott in 1996 and 1998 that the '815 patent provided "additional protection" for and "directly support[ed]" Zemplar. (JX42 at 1; JX47 at 2; Trial Tr. 189:7-21, 198:12-199:1, 215:18-216:18 (Dr. Cleare); Trial Tr. 528:18-529:6 (Mr. Thomas).) WARF ignored these conclusions when it categorized the '815 patent as "ancillary," and assigned it less than 1%

relative value.

- 100. WARF also knew at that time that the '815 patent represented a significant contribution to the development and commercialization of Zemplar. For example, WARF knew that physicians would have had significant concerns about administering a Vitamin D analog to patients having renal osteodystrophy, and particularly to certain patients, based on fears of causing or exacerbating hyperphosphatemia (elevated levels of serum phosphorous levels). (JX85, FOF ¶ 47; Trial Tr. 157:8-158:4 (Dr. DeLuca).) Dr. Slatopolsky's study that led to the '815 patent demonstrated for the first time that paricalcitol could suppress PTH (which is elevated in patients with chronic kidney disease) without leading to a dangerous increase in serum phosphorous levels and thus causing or exacerbating hyperphosphatemia. (Trial Tr. 128:1-15, 137:2-12, 138:7-17 (Dr. Slatopolsky); Trial Tr. 197:2-10, 227:16-228:21 (Dr. Cleare); JX188 at 1.)
- that led to the '815 patent was a gating item to the development of Zemplar. (JX5 at 26.) In 1993, WARF and Abbott entered into the 1993 Abbott License. (*Id.* at 1.) Appendix F to that license specifically referred to research to be performed by Dr. Slatopolsky as the first "Action" item for Abbott to complete under its "Development Plan" for paricalcitol. (*Id.* at 26; Trial Tr. 186:14-189:1 (Dr. Cleare).) In 1994, WARF received a copy of Abbott's 1993 Development Plan, in which Abbott referred to Dr. Slatopolsky's research as demonstrating that paricalcitol was the better candidate for developing into a drug because it both suppressed PTH and did not induce hypercalcemia. (JX86 at 4.) Dr. Slatopolsky's studies were again discussed in a March 1998 NDA Medical Review for Zemplar, copies of which were produced from WARF's files in this litigation, as demonstrating the advantages of paricalcitol over Calcijex. (JX52 at 6-7; Trial

Tr. 191:3-193:6 (Dr. Cleare).)

- 102. WARF also knew at the time of its initial valuation that the '815 patent was exclusively licensed to Abbott under the terms of the 1998 Abbott License, that it covered Zemplar's approved indication, and thus generated 7% "earned royalties" on Zemplar's sales. (JX426 at 105:7-17, 106:9-107:4, 109:6-14, 113:23-114:3 (Mr. Stoveken Rule 30(b)(6) testimony); JX47 at 1; Trial Tr. 1012:6-1015:17 (Dr. Severson); Trial Tr. 329:8-330:1, 334:19-335:4 (Dr. Cleare); Trial Tr. 542:15-544:19 (Mr. Thomas).)
- License that shared similar value characteristics to the '815 patent, to which WARF assigned 0.968% value, were WARF's '497 and '925 patents, to which WARF allocated 70% of the value of the portfolio. (Trial Tr. 1030:8-1033:8 (Dr. Severson); Trial Tr. 906:17-908:18 (Dr. Lentz); Trial Tr. 231:10-239:2 (Dr. Cleare); Trial Tr. 527:22-548:6 (Mr. Thomas); JX8; JX2-JX4, JX209-JX256.) WARF knew at the time of its initial valuation that the '815 patent was equally as valuable if not more valuable than the '497 and '925 patents. The '497 and '925 patents describe "many" different 19-nor Vitamin D compounds, including paricalcitol, without disclosing any bio data relating to paricalcitol or indeed, any Vitamin D2 compounds. (Trial Tr. 150:19-23, 153:8-18 (Dr. DeLuca); Trial Tr. 879:2-14 (Mr. Lentz).) Nor do the '497 and '925 patents contain any teachings about which of the "many" disclosed and claimed compounds could treat chronic kidney disease patients without causing dangerous increases in serum phosphorous. (Trial Tr. 163:9-24 (Dr. DeLuca); Trial Tr. 880:10-19 (Mr. Lentz); Trial Tr. 227:16-228:21 (Dr. Cleare); JX85, FOF ¶ 238-246; JX83 ¶ 100; JX2-JX4.)
- 104. For example, neither the '497 or '925 patents tested PTH levels and therefore did not directly establish whether any of the claimed compounds actually suppressed parathyroid

hormone. (Trial Tr. 163:9-19 (Dr. DeLuca).) In addition, neither patent tested the effect of any of the claimed compounds on serum phosphorous levels, which was important to establishing whether the claimed compounds could be used to treat secondary hyperparathyroidism without inducing the dangerous side effects of hyperphosphatemia. (Trial Tr. 163:20-24 (Dr. DeLuca); Trial Tr. 227:16-228:21 (Dr. Cleare); Trial Tr. 880:10-19 (Mr. Lentz); JX85, FOF ¶¶ 238-240; JX83 ¶ 100; JX2-JX4.)

- 105. By contrast, the '815 patent disclosed a study in uremic rats showing that paricalcitol suppressed PTH levels while causing only minimal increases in serum phosphorous levels across a wider therapeutic window, which helped show that Zemplar was safe and effective for use in patients with chronic kidney disease. (Trial Tr. 156:8-158:4 (Dr. DeLuca); Trial Tr. 197:2-198:11 (Dr. Cleare); JX85, FOF ¶¶ 334; JX52; JX82 ¶¶ 15, 24-27; JX188.)
- 106. WARF also knew at the time of its initial valuation that the '815 patent had a longer patent life than the '497 and '925 patents, providing an additional 1.55 years of patent protection over the '497 patent and an additional 3.24 years of patent protection over the '925 patent. (D.I. 154-1, Ex. 1, Uncontested Fact Nos. 20-21, 25; Trial Tr. 545:9-15 (Mr. Thomas).)
- Abbott License, which were solely owned by WARF, had little to no relationship to Zemplar but served only to benefit WARF by overallocating value to WARF's irrelevant and valueless patents at the expense of the parties co-owned '815 patent. Washington University's tech transfer expert, Dr. Cleare, reviewed all the Ancillary Patents in the 1998 Abbott License. Bringing to bear his education, training, and experience as a technology transfer expert, a Ph.D. in chemistry, and a named inventor on 10 pharmaceutical compound patents, Dr. Cleare analyzed what value, if any, WARF's solely-owned Ancillary Patents contributed to the manufacture, use,

or sale of Zemplar. (Trial Tr. 230:24-239:2 (Dr. Cleare).) Dr. Cleare concluded that 18 Ancillary Patents disclosed methods of manufacturing Vitamin D compounds other than the class of 19-nor Vitamin D compounds to which paricalcitol belongs. (Trial Tr. 232:24-235:12 (Dr. Cleare); JX209, JX210, JX211, JX212, JX213, JX214, JX215, JX216, JX217, JX219, JX220, JX221, JX222, JX223, JX224, JX226, JX227, JX249.) Because paricalcitol is a 19-nor Vitamin D compound, the methods disclosed in those 18 Ancillary Patents do not disclose processes for manufacturing paricalcitol. (E.g., Trial Tr. 233:17-234:10 (Dr. Cleare).) Those patents have no relation to Zemplar, provided no support to Zemplar in the marketplace, and generated no earned royalties to WARF. (Trial Tr. 233:17-234:10 (Dr. Cleare); Trial Tr. 555:6-556:5 (Mr. Thomas); Trial Tr. 505:3-20 (Mr. Stoveken); Trial Tr. 907:17-908:1 (Mr. Lentz); Trial Tr. 1030:17-24 (Dr. Severson); Trial Tr. 1108:21-1109:4 (Ms. Mulhern).) In addition, many of those patents had been filed in the 1980s — nearly a decade before Dr. DeLuca synthesized the class of 19-nor Vitamin D analogs claimed in the '497 and '925 patents — and therefore expired within 1-3 years of the execution of the 1998 Abbott License. (JX8 at 14-26 (showing expiration dates of all Ancillary Patents in the 1998 Abbott License); Trial Tr. 233:14-235:1 (Dr. Cleare); Trial Tr. 548:24-549:16 (Mr. Thomas).)

- 108. No WARF witness disputed Dr. Cleare's analysis that these 18 Ancillary Patents do not relate to making 19-nor Vitamin D compounds like paricalcitol. (Trial Tr. 907:17-908:1 (Mr. Lentz); Trial Tr. 1030:17-24 (Dr. Severson); Trial Tr. 1108:21-1109:4 (Ms. Mulhern).) Yet WARF's arbitrary and self-dealing relative value assignment allocated 18 times the value to this irrelevant group of WARF-owned patents as to the parties' co-owned '815 patent, which directly supported the development and commercialization of Zemplar. (JX12 at 11.)
 - 109. Dr. Cleare also concluded that 6 Ancillary Patents disclosed methods of using

paricalcitol for treating illnesses that had no relationship to Zemplar's approved use, including: (1) a patent for preventing transplant rejection, (2) a patent for treating symptoms of multiple sclerosis, (3) a patent for treating arthritic disease, (4) a patent for treating psoriasis, (5) a patent application relating to the prevention of transplant rejections, and (6) a patent for the treatment of immune deficiency. (Trial Tr. 235:13-237:13 (Dr. Cleare); JX238; JX248; JX253; JX254; JX246; JX251.) Unlike the '815 patent, which WARF knew "directly support[ed]" Zemplar and generated 7% earned royalties for WARF, this group of 6 Ancillary Patents did not cover any approved use of Zemplar, provided no support to its development and commercialization, and generated no earned royalties to WARF. (Trial Tr. 235:13-236:2 (Dr. Cleare); Trial Tr. 1108:21-1109:4 (Ms. Mulhern).) One of the "patents" in this group was actually a patent application relating to preventing transplant rejections that WARF had abandoned in January 1999. (Trial Tr. 480:13-481:10 (Mr. Surber); Trial Tr. 1002:17-1003:16 (Dr. Severson); JX246.)

110. No WARF witness disputed Dr. Cleare's analysis that these 6 Ancillary Patents had no relationship to Zemplar. (Trial Tr. 908:2-18 (Mr. Lentz); Trial Tr. 1031:1-12 (Dr. Severson); Trial Tr. 1108:21-1109:4 (Ms. Mulhern); Trial Tr. 162:11-163:6 (Dr. DeLuca).) Mr. Stoveken, who analyzed each patent in the Abbott portfolio in 2007 and 2008 with an eye to determining which ones supported Zemplar, admitted that the 6 Ancillary Patents in this group did relate to Zemplar. (D.I. 163-9, Ex. I at 51:22-66:19 (Mr. Stoveken).) Although WARF's technical expert, Mr. Lentz, testified that he believed assigning zero value to these patents would be "a bit harsh" because Abbott might have wanted to use them at some unspecified point in the future, Mr. Lentz admitted that Abbott never received FDA-approval for the indications recited in these 6 Ancillary Patents. (Trial Tr. 908:15-18 (Mr. Lentz).) Further, as the evidence at trial showed, WARF created *separate* relative value allocations to apply to anticipated new

indications, such as when WARF assigned 29% relative value to its multiple sclerosis treatment patent to be used "exclusively for royalty payments deriving from the Multiple Sclerosis field." (Trial Tr. 994:23-996:16 (Dr. Severson); JX15 at 2, 14-15.) By contrast, as applied to Zemplar royalties, WARF allocated 6 times the relative value to these WARF-owned treatment method patents that did not relate to Zemplar as it did to the co-owned '815 patent.

- 111. Dr. Cleare also concluded that one of the WARF-owned Ancillary Patents was entirely duplicative of the '497 patent and served no purpose other than to further inflate the value WARF allocated to its own patents at the expense of the parties' co-owned '815 patent. (Trial Tr. 237:14-238:7 (Dr. Cleare); JX252; JX377.) No WARF witness disputed Dr. Cleare's analysis on this point either. (Trial Tr. 1033:5-8 (Dr. Severson).)
- processes and/or intermediates for the manufacture of 19-nor Vitamin D compounds like paricalcitol. (Trial Tr. 238:8-239:2 (Dr. Cleare); JX225; JX232; JX229; JX230.) But, as Dr. DeLuca explained, none of those 4 Ancillary Patents would have been able to block generic competition for Zemplar because of the possibility that a competitor could design around those patents by taking advantage of multiple different chemical pathways to synthesize Zemplar. (D.I. 163-2, Ex. B at 117:12-22 (Dr. DeLuca).) WARF offered no evidence at trial to show that Abbott (or anyone else) manufactured Zemplar using any methods disclosed or claimed in these 4 Ancillary Patents. (D.I. 163-2, Ex. B at 67:17-19, 68:2-13 (Dr. DeLuca); Trial Tr. 829:18-830:4 (Mr. Lentz); Trial Tr. 1033:5-8 (Dr. Severson); Trial Tr. 1108:21-1109:4 (Ms. Mulhern).) Abbott paid no "earned royalties" on these patents. (Trial Tr. 505:3-20 (Mr. Stoveken); Trial Tr. 1108:21-1109:4 (Ms. Mulhern).) Further, these 4 Ancillary Patents could not have been listed in the Orange Book, which does not permit listing of process, manufacturing, and intermediate

patents. (Trial Tr. 290:8-20 (Dr. Cleare).) As a result, there is no evidence that these 4 Ancillary Patents supported the development or commercialization of Zemplar, generated earned royalties, or provided exclusivity over Zemplar. Yet WARF's arbitrary and self-dealing relative value assignment allocated 4 times the value to this group of WARF-owned patents as to the parties' co-owned '815 patent.

- 113. Dr. Cleare's analysis that 29 Ancillary Patents had no substantial value with respect to the manufacture, use, or sale of Zemplar stands unrebutted. WARF's licensing manager, Mr. Stoveken, testified that he reviewed each Ancillary Patent in 2008 to determine whether any patents that had a longer patent term that the '497 patent would be infringed by Zemplar but for a license and therefore would generate earned royalties for WARF. (Trial Tr. 505:3-20 (Mr. Stoveken).) Mr. Stoveken concluded that only the '815 patent met those criteria. (Trial Tr. 505:3-20 (Mr. Stoveken).) Dr. Severson admitted that no Ancillary Patent, other than the '815 patent, blocked generic competition for Zemplar, was listed in the Orange Book, was asserted in litigation, generated earned royalties, was licensed exclusively to Abbott, *or added any substantial value to Zemplar at all*. (Trial Tr. 1032:6-1033:8 (Dr. Severson).)
- affiliated university and its own inventors at the expense of Washington University and Dr. Slatopolsky. Not surprisingly, WARF believed that its relative valuation approach and its refusal to "rebalance" its allocations "worked beautifully" for WARF. (Trial Tr. 711:9-16 (Mr. Gulbrandsen).) WARF appropriated \$426.5 million in earned royalties from Abbott for itself, while remitting a little over \$1 million to Washington University. (JX476A at 1.)⁵

⁵ Specifically, WARF received \$427.6 million in "earned royalties" from Abbott based solely on the '497, '925, and '815 patents. (*Id.*). WARF allocated 0.968% — or only \$4.1 million — to the '815 patent. (*Id.*) WARF then paid itself nearly \$620,000 in administration fees in



claiming that it was merely following its supposed "policies" or "practices" of assigning value, which, WARF implies, was specifically authorized by the IIA. But the IIA does not authorize WARF to assign relative values "in accordance with WARF's policies." It says nothing about WARF's policies at all. It merely grants WARF "authority" to assign relative values, which required WARF to assign a fair value to the parties' co-owned '815 patent. (JX1 § 3(A)(iii); see also supra ¶¶ 43-44.) No valuation policies — and certainly none that would support WARF's assertion — were incorporated into the IIA as the standard by which WARF would assign value under the Relative Value Clause. Nor were any valuation policies disclosed during the parties'

[&]quot;consideration for securing and administering" the 1998 Abbott License on Washington University's behalf. WARF took \$2.3 million as WARF's two-thirds share in recognition of Dr. DeLuca's contributions as the compound owner, deducted over \$117,000 in patent expenses, and remitted only \$1,053,426 to Washington University. (*See* JX476A at 1-2.)

negotiations over the IIA. To the contrary, WARF insisted on building "flexibility" into the Relative Value Clause to preserve its ability to assign relative values in light of all the circumstances. (JX39 at 1; Trial Tr. 936:19-937:11, 980:10-22 (Dr. Severson); Trial Tr. 207:3-208:2 (Dr. Cleare).)

- 116. Moreover, WARF did not assign value to the '815 patent in accordance with its "policies." WARF produced only a single patent valuation policy from March 2011, which WARF represented was substantially the same as earlier policies. WARF's valuation policy gave WARF discretion to assign value based on a patent's "disproportionate value . . . in the development and commercialization of" the licensed products. (JX10 at 3.) In assigning value to the '815 patent, however, WARF did not follow this policy. As WARF candidly admits, it assigned value to the '815 patent without conducting any patent-specific evaluation at all indeed, ignoring its own conclusion from earlier in that same year that the '815 patent "directly support[ed]" Abbott's sale of Zemplar. (JX47 at 1; Trial Tr. 663:16-20 (Mr. Gulbrandsen).)
- treated WARF's wholly-owned "Ancillary Patents" in an Income Division Memo dated February 25, 1997 ("the Multiple Sclerosis IDM"). In the Multiple Sclerosis IDM, WARF assigned values to the Vitamin D patents licensed under a 1996 amendment to the 1993 Abbott License. The value allocations were to be applied "exclusively for royalty payments deriving from the Multiple Sclerosis field." (JX15 at 2.) Included among the Ancillary Patents in the 1993 Abbott License was a method of treatment patent for multiple sclerosis ("the Multiple Sclerosis Treatment Patent"). Thus, in the Multiple Sclerosis IDM like the Zemplar IDM WARF was assigning values between the Licensed Patents in Appendix B, and a method of treatment patent in the Ancillary Patents in Appendix C that WARF anticipated would support the licensed

product. (JX15 at 2.) However, unlike in the Zemplar IDM, WARF did not assign 70% to the Licensed Patents and allocate the remaining 30% equally to each Ancillary Patent regardless of their patent-specific contributions to the development and commercialization of the licensed product. Instead, WARF assigned *a full 29% relative value* to its multiple sclerosis treatment patent in the Ancillary group, while assigning only 42% to the Licensed Patents. In other words, WARF singled out its own method of treatment patent from the Ancillary group to receive 29 times the value that WARF assigned to the parties' co-owned '815 patent in a closely analogous valuation circumstance. (JX15 at 2, 14-15; Trial Tr. 994:18-998:17 (Dr. Severson).)

118. As WARF's own tech transfer expert. Dr. Severson, admitted, WARF's duty to be fair to Washington University under the IIA precluded WARF from applying a more favorable standard to its solely-owned WARF patents than the one it applied to the parties' co-owned '815 patent. (Trial Tr. 1000:21-18, 1009:2-7 (Dr. Severson).) Yet that is exactly what WARF did. WARF has never explained why it applied a much more favorable standard to its own Ancillary Patent in the Multiple Sclerosis IDM than the one it applied to the parties' co-owned '815 patent in the Zemplar IDM. When Washington University asked WARF's tech transfer expert, Dr. Severson, to reconcile WARF's differential treatment of the two ancillary patents, he answered that WARF's written policy *allowed* WARF to single out ancillary patents to receive substantial relative value depending on their contribution to the development and commercialization of the licensed drug. (Trial Tr. 996:17-998:13 (Dr. Severson).) Yet, despite WARF's knowledge that the '815 patent "directly support[ed]" Zemplar, WARF ignored that information, performed no patent-specific evaluation of the '815 patent at all, and assigned it negligible value.

- G. WARF Provides Washington University with a False and Misleading Explanation of Its Relative Value Assignment
- 119. As noted above, WARF first assigned a relative value to the '815 patent by at

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least October 16, 1998, as reflected in an internal memorandum prepared by Mr. Kirkpatrick at WARF, describing how WARF assigned value to the parties' co-owned '815 patent relative to WARF's patents in the Abbott portfolio. (JX12 at 15-16; Trial Tr. 199:23-202:7 (Dr. Cleare).)

- 120. As the junior party, Washington University reasonably expected that WARF would share information about the '815 patent's comparative value with Washington University and discuss its relative value analysis *before* it began distributing Washington University's share of the royalty payments, particularly in light of WARF's promise to "use all reasonable efforts to cooperate" with Washington University regarding WARF's licensing activities. (JX1 § 2(A)(iii); Trial Tr. 179:20-180:5 (Dr. Cleare); Trial Tr. 353:19-355:7, 355:16-357:10 (Dr. Brandt); Trial Tr. 380:15-381:6 (Kratochvil).)
- letter to Washington University on October 26, 1998 for the stated purpose of providing "an update regarding our above-referenced agreement." (JX48 at 1.) Even though Ms. Kirkpatrick knew WARF had already assigned a 0.968% relative value to the '815 patent, Ms. Kirkpatrick did not tell Washington University that WARF had completed its relative valuation. (*See id.*; Trial Tr. 202:19-204:5 (Dr. Cleare).) Nor did Ms. Kirkpatrick disclose *any* information about the '815 patent's relative value to Washington University, including her statement to Abbott a few months earlier that the '815 patent "directly supports" Zemplar. (JX48 at 1) Instead, Ms. Kirkpatrick informed Washington University that WARF had received the "first royalties for the Zemplar® product" on "September 21st, 1998," and planned to provide Washington University with its first disbursement "by August 31st, 1999" pursuant to the IIA's Annual Payment Provision. (*Id.*) Ms. Kirkpatrick wrote that WARF "will provide full details regarding the calculation used to determine Washington University's distribution" at that time. (*Id.*)

- Washington University, attaching a check for \$131.69, stating: "Contrary to my previous letter, enclosed please find a disbursement based on the first royalty revenue received from Abbott Laboratories for their product Zemplar®." (JX21 at 1.) By way of explanation for why "the royalties received are relatively low," Mr. Kirkpatrick explained that Abbott had "launched this product in late May and are still in the ramp-up phase in converting sales from their Calcijex® product" while never mentioning WARF's 0.968% relative valuation performed one month earlier. (*Id.*) Although Ms. Kirkpatrick included *some* "calculations for the disbursed amount" by listing the "Royalty Income" (\$929.66) and WARF's deductions under the IIA, Ms. Kirkpatrick concealed how WARF had calculated the top-line "Royalty Income" number *i.e.*, that it represented less than 1% of the royalties WARF had received from Abbott. (*Id.*)
- the relative value WARF had assigned to the parties' co-owned '815 patent, along with WARF's concealment of the information it possessed about the '815 patent's central importance to the development and commercialization of Zemplar, violated WARF's obligations under the IIA and represented a significant departure from common practices in the university tech transfer industry. (Trial Tr. 982:8-12, 983:15-18 (Dr. Severson); Trial Tr. 175:19-182:15 (Dr. Cleare); Trial Tr. 351:3-355:7, 371:22-372:7 (Dr. Brandt); Trial Tr. 380:5-381:6 (Mr. Kratochvil); Trial Tr. 423:4-424:6 (Mr. Surber).) As the junior party paying a 15% administration fee to WARF, who promised to administer all license agreements for the parties "mutual benefit" and "use reasonable efforts to cooperate" with Washington University with respect to "licensing," Washington University reasonably expected that WARF would share information about the value of the '815 patent and not engage in a self-dealing relative valuation. (*See id.*)

- 124. It wasn't until two and a half years later on April 4, 2001 and in response to a specific request by Washington University that WARF provided Washington University with details about how WARF calculated the top line "Revenue" number *i.e.*, what relative value it had assigned to the '815 patent. (JX49 at 1; Trial Tr. 203:15-204:13 (Dr. Cleare).) WARF's April 4, 2001 letter was sent by Jodie Armstrong to an account administrator at Washington University, Kay Jinkerson, copying WARF's General Counsel Elizabeth Donley. (JX49 at 1.)
- 125. In its April 4, 2001 letter, WARF provided the following explanation of the relative value it had assigned to the parties' co-owned '815 patent:

You had asked for some additional information regarding how [WARF] decides on the percentage of total royalties it pays to [Washington University] under the above-referenced Agreement. As you know, we provide an accounting of the calculation of royalties with each check that we send you; however, your question relates more specifically to the percentage of the total royalty dollars received by WARF that is shared with [Washington University] under the [1995 IIA].

The License Agreement from which royalties are generated has a portfolio of patents relating to the Vitamin D compound that is licensed. The compound patents are allocated seventy percent (70%) of the total royalty income in accordance with WARF's regular practice in licensing and allocating royalties in a suite of patents for its Vitamin D portfolio. In addition, there are thirty one (31) ancillary patents included in the license agreement, including the patent that is the subject of the [1995 IIA]. Each of the patents in the ancillary patent portfolio is allocated an equal share of the remaining thirty percent (30%) of the royalties generated by the License Agreement. It is WARF's policy to allocate evenly among these patents regardless of whether or not the patent is actually currently being used by the Licensee. This is because, in many cases, it is difficult if not impossible for WARF to determine whether or not the patent is being used by the Licensee at this time. However, WARF believes that the patent adds some value to the entire portfolio and that, since the license runs to the last of the patents to expire there should be some blending over the lifetime of the License so that all patents in the License benefit from having been licensed. . . .

Therefore, under the terms of the Interinstitutional Agreement [Washington University] receives one third of .968 percent of the total royalties generated under the license agreement WARF has with its licensee."

(JX49 at 1-2.)

126. As WARF's own tech transfer expert acknowledged, WARF had an obligation

under the IIA to provide Washington University with honest and accurate information in WARF's April 4, 2001 letter to Washington University. (Trial Tr. 990:16-20 (Dr. Severson).) Yet WARF's explanation for its relative value assignment was full of misstatements, half-truths, and misdirection. (*See generally* JX49 at 1-2; Trial Tr. 990:11-1003:16, 1009:2-4 (Dr. Severson); Trial Tr. 203:2-204:13, 208:13-212:4, 216:19-217:16 (Dr. Cleare); Trial Tr. 476:5-483:14 (Mr. Surber).)

- 127. First, WARF misrepresented that "[t]he License Agreement from which royalties are generated has a portfolio of patents relating to the Vitamin D compound that is licensed."

 (JX49 at 1.) The 1998 Abbott License that generated "earned royalties" from the sale of Zemplar granted rights to only a *single* compound, the 19-nor Vitamin D2 analog "paricalcitol."

 (JX8 at 11; Trial Tr. 782:15-20 (Mr. Lentz); Trial Tr. 324:7-325:12 (Mr. Cleare).) As Dr. Cleare's analysis of the Ancillary Patents showed, the 1998 Abbott License contained 18 Ancillary Patents that did not relate to making 19-nor Vitamin D analogs at all. Those patents pertained to methods of making Vitamin D2 and Vitamin D3 compounds that Dr. DeLuca had patented in the early 1980s, nearly a decade before he first synthesized the 19-nor Vitamin D2 analog paricalcitol. (Trial Tr. 233:17-235:1 (Dr. Cleare).) No WARF witness attempted to rebut these facts. (*See* Trial Tr. 907:17-908:1 (Mr. Lentz); Trial Tr. 1030:8-24 (Dr. Severson).)
- Abbott contained a portfolio of patents related to *the* licensed Vitamin D compound, when it fact many of those patents were unrelated to paricalcitol. (Trial Tr. 475:23-477:8 (Mr. Surber).) If WARF had told the truth to Washington University, Washington University could have realized that not all patents in the Ancillary Patents group related to the licensed compound a key point that distinguished the '815 patent from the majority of patents in that group and raised a

challenge to WARF's relative valuation. But because WARF denied Washington University a copy of the 1998 Abbott License based on non-existent "confidentiality provisions," Washington University could not evaluate for itself WARF's representation that all patents in the Abbott portfolio related to paricalcitol. (Trial Tr. 989:12-22 (Dr. Severson).)

- Second, WARF misrepresented that "[t]he compound patents are allocated seventy percent (70%) of the total royalty income in accordance with WARF's regular practice in licensing and allocating royalties in a suite of patents for its Vitamin D portfolio." (JX49 at 1.) This sentence contains at least two highly material, false, and misleading representations:

 (1) that WARF had, in fact, assigned 70% relative value only to "compound patents" and (2) that WARF had a "regular practice" of allocating 70% relative value only to "compound patents."
- represented that only "compound patents" were included in the 70% relative value group. Dr. Severson agreed that "[t]here was *only one compound patent* in the 70 percent group of the 1998 Abbott License" WARF's '497 patent (Trial Tr. 991:11-14 (Dr. Severson) (emphasis added).) Dr. Severson also agreed that "[t]he other patent in the group was the '925 patent, *which was a method of treatment patent*" *i.e.*, a non-compound patent of the same type as the parties' co-owned '815 patent. (Trial Tr. 991:15-23 (Dr. Severson) (emphasis added).) As Dr. Severson acknowledged, by including the '925 patent in the 70% royalty group, WARF had allocated a full 35% relative value to that patent alone. (Trial Tr. 992:6-993:2 (Dr. Severson); *see also* JX10 at 3 ("Under WARF's process, the original U.S. patent filing of each Patent Family in an agreement, as well as any CIPs, are treated individually and equally, unless unequal percentages are assigned by the Licensing Manager.").) WARF's misrepresentation created the false impression that WARF had a practice of assigning substantial relative value only the compound

patents, not method of treatment patents like the '815 patent. (Trial Tr. 477:9-478:4 (Mr. Surber).)

- WARF used the internal moniker "compound patents" to refer to the '497 and '925 patents. Yet WARF had no trouble explaining internally in its October 16, 1998 valuation memorandum that "the compound *and the primary indication[]* will receive a relative value of 70%." (JX12 at 16 (emphasis added).) Notably, the recipient of that internal memorandum Jodie Armstrong was the same person who authored the April 4, 2001 letter to Washington University, and WARF's General Counsel Beth Donley was copied on both documents. (JX12 at 15; JX49 at 2.) WARF provided no explanation why it failed to convey this same level of information to Washington University. In any event, as WARF's tech transfer expert admitted, WARF never told Washington University about its alleged use of the term "compound patents" as an internal moniker to refer to a compound patent and a method of treatment that directly related to the primary indication. (Trial Tr. 991:15-992:5, 993:15-23 (Dr. Severson).)
- of allocating 70% relative value only to "compound patents" was also false. WARF had no such "regular practice." (*See, e.g.*, Trial Tr. 213:18-215:12 (Dr. Cleare); Trial Tr. 996:17-999:9 (Dr. Severson).) WARF's relative value assignments in other Vitamin D portfolio licenses did not adhere to this 70% / 30% split. In connection with Vitamin D portfolio licenses to Tetrionics, Deltanoid, Quatrx, and Buyske, WARF sometimes allocated 60% and sometimes 80% to the Licensed Patents group. (JX16-JX20; *see also* 214:19-215:12 (Dr. Cleare).) And, as noted above, in connection with WARF's Multiple Sclerosis IDM, WARF assigned only 42% relative value to the Licensed Patents group. (JX15 at 2, 14; Trial Tr. 994:23-995:22 (Dr.

Severson).) WARF assigned 29% to a single Multiple Sclerosis patent in the Ancillary Patents group, and allocated 29% to all remaining Ancillary Patents. (JX15 at 14-15; Trial Tr. 995:23-996:16 (Dr. Severson).) WARF's assertion, therefore, misleadingly conveyed that WARF had merely followed its routine practices when assigning value to the '815 patent, when in fact it had not. (Trial Tr. 478:5-22 (Mr. Surber).)

WARF's actual policies and practices contradict WARF's assertion that it had "a 133. regular practice" of allocating 70% relative value to the "compound patents" when licensing and allocating royalties in a suite of patents for WARF's Vitamin D portfolio. Not only did WARF allocate 35% of the Zemplar royalty stream to its own '925 patented treatment method that covered Zemplar's approved use, while representing to Washington University that only "compound patents" received substantial value under WARF's regular practices, but WARF also assigned a full 29% value to its own multiple sclerosis treatment patent in the Ancillary group to apply to any revenue deriving from the Multiple Sclerosis Field. (JX49; JX15; JX12; Trial Tr. 213:18-215:12 (Dr. Cleare); Trial Tr. 994:18-22 (Dr. Severson).) WARF's assertion that the 70% relative value group contained only "compound patents" and that it had a "regular practice" of assigning 70% to those patents, coupled with WARF's earlier refusal to share the Abbott license agreements with Washington University based on "confidentiality provisions" that did not in fact exist, prevented Washington University from evaluating the accuracy and relevance of the 70% value that WARF stated it had allocated to the "compound patents." In particular, WARF's conduct had the effect of supporting WARF's claims (which were incorrect) that WARF had a regular practice of assigning substantial relative value only to "compound patents," and that treatment method patents like the '815 patent were not entitled to substantial relative value. (Trial Tr. 209:12-210:20 (Dr. Cleare); Trial Tr. 478:5-22 (Mr. Surber.) Washington

University learned the truth only through civil discovery, after receiving the 1998 Abbott License, WARF's written valuation policy, and WARF's Multiple Sclerosis IDM. (Trial Tr. 998:14-999:9 (Dr. Severson).)

134 **Third**, for similar reasons, WARF misrepresented that "[i]t is WARF's policy to allocate evenly among [the Ancillary Patents] regardless of whether or not the patent is actually currently being used by the Licensee." (JX 49 at 1.) WARF's tech transfer expert, Dr. Severson, admitted that he had never seen any WARF policy embodying that statement. (Trial Tr. 994:8-17 (Dr. Severson).) WARF's statement did not align with WARF's general practices for allocating value among Ancillary Patents in the Vitamin D portfolio, as evidenced by WARF's preferential treatment of its multiple sclerosis ancillary patent in the Multiple Sclerosis IDM. (JX15 at 14-15; Trial Tr. 994:23-996:16 (Dr. Severson).) When asked to reconcile WARF's unequal allocation of relative value to the multiple sclerosis ancillary patent with WARF's assertion that it had a policy (or practice) of assigning equal value to all ancillary patents, Dr. Severson could not do so. (Trial Tr. 996:17-998:13 (Dr. Severson).) Instead, he admitted that WARF's written policy gave WARF discretion to assign unequal relative value to any patent based on its disproportionate "contribution to the development and commercialization" to the licensed drug, and that it made no distinction between "Licensed Patents" and "Ancillary Patents." (Trial Tr. 996:17-998:13 (Dr. Severson); JX10 at 3.) WARF's assertion misleadingly conveyed that WARF had a regular practice of assigning equal value to all ancillary patents regardless of use, when in fact it did not. (Trial Tr. 481:11-482:5 (Mr. Surber.) Washington University learned the truth only through civil discovery when it received WARF's actual valuation policy and learned of WARF's actual valuation practices. (Trial Tr. 993:15-994:22, 998:22-999:9 (Dr. Severson).)

- Washington University, and that such fairness meant WARF could not apply a more favorable valuation standard to WARF's patents than the standard it applied to the parties' co-owned '815 patent. (Trial Tr. 982:8-12, 983:15-18, 1000:21-1001:18, 1009:2-7 (Dr. Severson).) The IIA's Mutual Benefit and Cooperation Clauses imposed the same obligations. (JX1 §§ 2(A)(iii), 2(B)(ii).) WARF violated its contractual and professional obligations to Washington University when it dealt with the co-owned '815 patent under a less preferential standard than the one contained in WARF's written valuation policy, and misrepresented that WARF's policy required equal allocation to all ancillary patents regardless of the patent's use, when that simply wasn't true. Again, if Washington University had known the truth, Washington University could have raised an appropriate challenge. (Trial Tr. 1029:17-24 (Dr. Severson).)
- Patents regardless of their use *i.e.*, that "[t]his is because, in many cases, *it is difficult if not impossible for WARF to determine whether or not the patent is being used* by the Licensee at this time" (JX49 at 1 (emphasis added) created the false impression that WARF was unable to determine whether any of the Ancillary Patents, including the '815 patent, supported the development and commercialization of Zemplar. Yet WARF had previously determined and concealed from Washington University that the '815 patent "*directly support[ed]*" Zemplar. (JX47 at 1 (emphasis added).) WARF knew the '815 patent study had helped convince the FDA and physicians that Zemplar represented a significant advance over Calcijex. (*See supra* ¶ 43.) And at the time WARF made this assertion, WARF knew that over half a dozen WARF-owned patents had already expired or been abandoned, including WARF's abandoned transplant rejection patent application, which WARF abandoned in January 1999, with no possibility of

"being used" by Abbott at that time. (JX8 at 13-20; Trial Tr. 1002:19-1003:16 (Dr. Severson).)

- 137. Again, only through civil discovery did Washington University learn that WARF had already determined that the '815 patent's covered Zemplar's approved use, ignored that conclusion when assigning a relative value to the parties' co-owned patent, concealed that information from Washington University, and misrepresented WARF's state of knowledge. (*See supra* ¶ 44.)
- 138. WARF's deceptive assertions, half-truths, and misinformation violated WARF's contractual and professional obligations under the IIA. Under the IIA, WARF promised to "use all reasonable efforts to cooperate" with Washington University, and to administer all license agreements for the parties' "mutual benefit." (JX1 §§ 2(A)(iii), 2(B)(ii).) In addition, as WARF's own tech transfer expert, Dr. Severson, admitted, WARF had a duty to be honest in its dealings under the IIA, and to provide Washington University with honest and accurate information in the April 4, 2001 letter. (Trial Tr. 983:15-18, 990:16-20 (Dr. Severson).) WARF's April 4, 2001 letter did not live up to WARF's promises and professional obligations.
- April 4, 2001 letter. Having delegated and entrusted the '815 patent's commercialization to WARF under the commitments contained in the IIA, and having been promised that WARF would "cooperate" with Washington University and act for the parties' "mutual benefit," Washington University reasonably relied on the assumption that WARF was acting at all times in accordance with WARF's contractual and professional obligations under the IIA. (*See* JX1 §§ 2(A)(iii), 2(B)(ii); Trial Tr. 353:19-355:7, 356:15-19, 361:20-362:6, 363:1-18, 363:19-364:13 (Dr. Brandt); Trial Tr. 391:12-392:12 (Mr. Kratochvil).) Washington University, as the junior party, reasonably expected that WARF, as the senior party, would share key information known

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to WARF about the contribution of the parties' co-owned '815 patent to Abbott's development and commercialization of Zemplar. (Trial Tr. 177:3-20, 178:12-179:19 (Dr. Cleare); Trial Tr. 353:19-355:7, 363:19-364:13 (Dr. Brandt); Trial Tr. 391:12-21 (Mr. Kratochvil) ("We are the junior party, we shouldn't be reaching out to the senior party to find information that should be provided to us.").) Washington University also reasonably relied upon WARF's professional obligations to deal with Washington University in a fair and collegial manner (Trial Tr. 982:8-12 (Dr. Severson)), use all known information about the '815 patent's value when assigning relative values under the IIA (Trial Tr. 983:7-14 (Dr. Severson); Trial Tr. 184:11-21 (Dr. Cleare)), assign relative values fairly and in good faith (Trial Tr. 982:4-7 (Dr. Severson)), and provide honest and accurate information about WARF's valuation policies, practices, and conclusions to Washington University (Trial Tr. 983:15-18, 990:16-20 (Dr. Severson)). Washington University's reliance was all the more reasonably in light of Washington University's payment of nearly \$620,000 in administration fees as consideration for WARF's administration of the Abbott license agreement for the parties' mutual benefit. (Trial Tr. 181:7-24 (Dr. Cleare).)

University had no obligation to exercise oversight over WARF. (Trial Tr. 1003:17-20 (Dr. Severson); *see also* Trial Tr. 229:22-230:23 (Dr. Cleare); Trial Tr. 384:17-21 (Mr. Kratochvil).) Washington University also had no reasons to suspect that WARF was not being honest and forthcoming in its communications. (Trial Tr. 990:6-10 (Dr. Severson).) Because WARF actively concealed from Washington University all relevant information about the value of the '815 patent and the information that Washington University needed to evaluate WARF's assertions about the patent's relative value, Washington University had no reason to believe that WARF had falsely represented that the '815 patent was "ancillary" to Zemplar and worth

negligible value compared to WARF's patents.

H. WARF Continues to Keep Washington University in the Dark About the '815 Patent's Relative Value

- 141. WARF made small annual payments to Washington University from its Zemplar licensing revenues based on the paltry 0.968% value WARF had assigned to the '815 patent. (Trial Tr. 1105:3-23 (Ms. Mulhern); JX476A at 1.) Over that time period, WARF did not provide Washington University with any additional information about the licensing, enforcement, treatment, or characterization of the '815 patent, or correct any of its misleading and false statements in its April 4, 2001 letter. Nor did WARF disclose that it had assigned a grossly deficient relative value to the '815 patent or volunteer to correct it.
- 142. Instead, as detailed below, WARF continued to conceal information about the value of the '815 patent from Washington University, including by concealing from Washington University (1) a patent valuation analysis that WARF performed in 2008 that "rediscovered" that the '815 patent covered Zemplar, (2) Abbott and WARF's decision to list the '815 patent in the Orange Book for Zemplar in 2011 (JX93, 95, 415), and (3) Abbott and WARF's assertion of the '815 patent in litigation to block generic competition for Zemplar. (JX58-59, 64.)

1. Mr. Stoveken's "Good News" Email in 2008

143. In 2008, a relatively new hire at WARF (Mr. Stoveken) undertook a review of all the patents in the 1998 Abbott License to determine whether any patents with a longer patent term than the '497 patent would have been infringed by Zemplar but for the license agreement. (Trial Tr. 504:8-21 (Mr. Stoveken); (D.I. 163-9, Ex. I at 76:25-77:2 (Mr. Stoveken).) The purpose of Mr. Stoveken's review was to determine whether there were any patents subject to the 1998 Abbott License that "would still have any value" after expiration of the '497 patent. (Trial Tr. 503:17-504:7 (Mr. Stoveken).) Mr. Stoveken's review led him to conclude that the '815

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patent was the only patent in the 1998 Abbott License with a longer patent term than the '497 patent that practiced Zemplar. (JX50 at 1; Trial Tr. 504:22-505:10 (Mr. Stoveken).)

144. In an internal WARF email that Mr. Stoveken wrote on October 14, 2008 to WARF's Director of Licensing, Craig Christenson (JX50 at 1; Trial Tr. 502:21-24 (Mr. Stoveken)), Mr. Stoveken explained his findings and conclusions:

Hi Craig,

The reason I was looking to catch up with you this afternoon was to go over a claim in one of the patents that was in the Zemplar license to Abbott. The patent was titled Prevention of Hyperphosphatemia with 19 nor Vitamin D Compounds; which based on the title, did not appear to be relevant for make, use, sell, have sold etc. However, when I read the claims I noted that the lead claim is for use of 19 nor compounds to treat renal osteodystrophy while preventing or minimizing serum phosphorous levels in the blood. This is exactly the application and population Abbott targets and sells Zemplar for with the exception that it is indicated for reducing parathyroid hormone. Elevated levels of parathyroid hormone are the cause of renal osteodystrophy so SHPT = renal osteodystrophy because SHPT is what causes the disease. So, thinking ahead, if there is any question about the applicability of the first claim I tend to think it will most likely be resolved based on an inherency argument. In any case, the reality [is that] Abbott does market [Zemplar] to [sic] for use in patients with renal osteodystrophy.

I'll have Melodie send you a PDF of the patent for you to look over and then schedule a meeting with everyone for late next week. I don't want to get everyone too excited about this until we all have a chance to challenge the thinking around this, but I sense we have some good news here. Have a good time in China and we'll talk more when you return.

(JX50 at 1.)

145. Mr. Stoveken's statement that, at first blush, the '815 patent "did not appear to be relevant for make, use, sell, have sold," reflected the mismatch between the '815 patent claims' recitation of a renal osteodystrophy (RO) treatment method and the FDA's approved indication of Zemplar for treating secondary hyperparathyroidism (SHPT). (JX50 at 1; Trial Tr. 506:2-507:2, 508:16-21 (Mr. Stoveken).) However, as Mr. Stoveken considered his knowledge of how Abbott marketed Zemplar, Mr. Stoveken realized that the '815 patent was "exactly the

application and population Abbott targets and sells Zemplar for" because "SHPT = renal osteodystrophy" and "the reality [is that] Abbott does market to [sic] for use in patients with renal osteodystrophy." (JX50 at 1; Trial Tr. 507:3-509:3 (Mr. Stoveken).)

- 146. Mr. Stoveken emphasized in his email that this was "good news" because it meant that the '815 patent would continue to generate royalties under the 1998 Abbott Agreement after expiration of the '497 patent. (JX50 at 1; Trial Tr. 509:13-511:12 (Mr. Stoveken).)
- value that WARF assigned to the '815 patent, but also with WARF's prior justification for it *i.e.*, its assertion in the April 4, 2001 letter that "it [was] difficult if not impossible for WARF to determine whether or not the patent [was] being used by [Abbott] at this time." (JX49 at 1.) At no time did WARF share with Washington University the "good news" in Mr. Stoveken's email, nor alert Washington University that WARF's initial valuation had been based on a mistake, as one might expect if WARF had unintentionally and in good faith made an original valuation error. (Trial Tr. 511:13-512:1 (Mr. Stoveken); Trial Tr. 219:20-220:12 (Dr. Cleare).)

2. The '815 Patent's Listing in the Orange Book in 2011

- 148. In 2011, Abbott notified WARF that it intended to list the '815 patent in the Orange Book, and asked whether WARF would have any objection to that (which WARF did not). (Trial Tr. 721:20-722:6 (Mr. Gulbrandsen).) WARF did not convey this important information to Washington University. (Trial Tr. 722:7-10 (Mr. Gulbrandsen); Trial Tr. 418:3-8 (Mr. Surber).)
- 149. Under the regulatory scheme established by the Hatch-Waxman Act, a patent that is listed in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the "Orange Book," can give rise to additional, automatic exclusivity benefits against generic competition by delaying FDA approval of the generic drug. (Trial Tr.

897:9-898:14, 902:17-904:1 (Mr. Lentz).) The Hatch-Waxman framework allows for the "late listing" of patents in the Orange Book. (Trial Tr. 838:9-18, 915:4-10 (Mr. Lentz).) As WARF's patent licensing expert, Mr. Lentz, admitted, those who "late list" a patent in the Orange Book can still obtain the benefit of a 30-month stay with respect to ANDA applications filed after the Orange Book listing." (Trial Tr. 906:10-16 (Mr. Lentz).)

- a drug represents that the patent claims the drug or a method of using the drug and a claim of patent infringement could reasonably be asserted against an unlicensed generic competitor. (Trial Tr. 854:11-18 (Mr. Lentz); JX478.) If an Orange Book listed patent covers the drug in question, the generic manufacturer must submit either a "Paragraph III" certification stating that the generic manufacturer will stay off the market until the listed patent has expired, or a "Paragraph IV" certification stating that the listed patent is invalid or would not be infringed by the generic drug. (Trial Tr. 897:9-898:14, 902:17-904:1 (Mr. Lentz).) If the generic manufacturer files a Paragraph IV certification, the patent owner may sue that entity for patent infringement within 45 days of notice of the certification. In that event, FDA approval of the ANDA application is automatically stayed for 30 months. (Trial Tr. 897:9-898:14, 902:17-904:1 (Mr. Lentz).)
- 151. Mr. Lentz admitted he had no way of knowing how many generic companies filed Paragraph III certifications, effectively agreeing to remain off the market until the expiration of the '815 patent. (Trial Tr. 898:4-10 (Mr. Lentz).)
- 152. With respect to generic companies that filed Paragraph IV certifications, Mr. Lentz acknowledged that a 30-month stay came into force with reference to generic companies that WARF and Abbott had sued for infringing the '815 patent, and would have remained in

force absent a settlement agreement, the expiration of the '815 patent, or a district court judgment of noninfringement or invalidity. (Trial Tr. 902:17-904:1 (Mr. Lentz).)

- 153. The Orange Book listed only five patents for Zemplar. Of those, three, including the '815 patent, were WARF-owned in part or in whole. (JX93A; JX95.) This meant that the '815 patent was one of only three patents that WARF licensed to Abbott under the 1998 Abbott License that covered Zemplar or its approved use, and therefore protected Zemplar's exclusivity and generated "earned royalties." (Trial Tr. 531:9-23 (Mr. Thomas).)
- valuable tool in maintaining Zemplar's market exclusivity, and further confirmed the '815 patent's substantial value. (Trial Tr. 903:4-904:1 (Mr. Lentz); Trial Tr. 531:9-532:7 (Mr. Thomas).) The Orange Book listing was also inconsistent with WARF's explanation to Washington University for the '815 patent's low value *i.e.*, its assertion in the 2001 letter that "it [was] difficult if not impossible for WARF to determine whether or not the patent [was] being used by [Abbott] at this time." (JX49.) In order to list the '815 patent in the Orange Book, Abbott needed to certify under penalty of perjury that the '815 patent covered Zemplar's approved use. (Trial Tr. 854:7-18 (Mr. Lentz).) The listing of the '815 patent in the Orange

Book for Zemplar was therefore a representation that Abbott was using the patent. (JX415.)

155. Far from being "ancillary" or meriting a sub-one percent relative value, the '815 patent was in fact a core patent within the Abbott License portfolio. (*See supra* ¶¶ 67, 70, 73, 75-77, 80-85, 89-94, 99-113..) At no time did WARF the Orange Book listing to Washington University's attention. (Trial Tr. 722:7-10 (Mr. Gulbrandsen); Trial Tr. 418:3-8 (Mr. Surber).)

3. The '815 Patent's Assertion in Litigation Beginning in 2012

- 156. Unbeknown to Washington University, WARF and Abbott began filing patent infringement lawsuits in the District of Delaware that prominently featured the '815 patent. (Trial Tr. 220:13-222:15 (Dr. Cleare); Trial Tr. 400:8-11, 418:9-22, 433:9-15, 437:14-21 (Mr. Surber); Trial Tr. 904:2-6 (Mr. Lentz); JX58-60; JX63-66; JX416.)
 - 157. WARF and Abbott asserted the '815 patent in at least eight lawsuits in this Court:
 - a. *Abbott Labs. et al. v. Hospira, Inc.*, Case No. 1:12-cv-00234-GMS (D. Del. Feb. 27, 2012).
 - b. *Abbott Labs. et al. v. Agila Specialties Private Ltd.*, Case No. 1:12-cv-00520-GMS (D. Del. Apr. 25, 2012).
 - c. *Abbott Labs. et al. v. Sandoz, Inc.*, Case No. 1:12-cv-00836-GMS (D. Del. June 29, 2012).;
 - d. AbbVie Inc. et al. v. Banner Pharmacaps Inc., Case No. 1:12-cv-01228-GMS (D. Del. Sept. 28, 2012).
 - e. *AbbVie Inc. et al. v. Sun Pharma Indus. Ltd.*, Case No. 1:13-cv-00138-GMS (D. Del. Jan. 24, 2013).
 - f. AbbVie Inc. et al. v. Dr. Reddy's Labs. Ltd. et al., Case No. 1:99-mc-09999 (D. Del. June 5, 2013).
 - g. *AbbVie Inc. et al. v. Hikma Pharma Co., Ltd. et al.*, Case No. 1:13-cv-01557-UNA (D. Del. Sept. 13, 2013).
 - h. AbbVie et al. v. Aurobindo Pharma Ltd., Case No. 1:14-cv-00215-UNA (D. Del. Feb. 19, 2014).

(Trial Tr. 532:8-13, 547:16-548:6, 607:22-608:1 (Mr. Thomas); JX58-60; JX63-66; JX416.)

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- 158. In three of those cases the *Banner*, *Sun*, and *Hikma* cases the '815 patent was the *only* patent asserted and thus the *only* means for WARF and Abbott to maintain Zemplar's market exclusivity. (Trial Tr. 294:2-5 (Dr. Cleare); Trial Tr. 532:8-13, 547:16-548:6 (Mr. Thomas); Trial Tr. 852:14-17, 854:1-6 (Mr. Lentz); JX59-60; JX66.)
- 159. Meanwhile, WARF continued to pay Washington University as if the '815 patent were worth no more than the dozens of other Ancillary Patents in the 1998 Abbott License even though those patents have *never* been asserted to protect Zemplar, the sole revenue generator under that license. (Trial Tr. 1032:12-22 (Dr. Severson); Trial Tr. 231:10-239:2 (Dr. Cleare); Trial Tr. 548:7-550:7, 555:6-556:5; 586:22-587:1, 590:15-591:5, 591:10-24, 592:16-593:1 (Mr. Thomas).)
- 160. WARF did not discuss its decision to file those actions with Washington University or otherwise inform Washington University before it filed those actions. (Trial Tr. 220:13-222:15 (Dr. Cleare); Trial Tr. 400:8-11, 418:9-22, 433:9-15, 437:14-21 (Mr. Surber).)
- 161. Furthermore, because WARF recorded incorrect patent assignment information with the USPTO (JX56 at 2) and incorrectly asserted that WARF was the sole owner of the '815 patent in complaints filed in this Court against generic manufacturers, Washington University

⁶ Consistent with WARF's obligations as the senior party to the IIA, WARF also took the lead in recording patent assignment information with the USPTO. (JX1 at § 2.A.(i), (iii).) On October 30, 1995, Dr. Eduardo Slatopolsky assigned his interest in the '815 patent application to Washington University. (JX193.) On November 7, 1995, Washington University wrote a letter to WARF enclosing a copy of the patent assignment, and asking WARF to record it in the USPTO and return a copy to Washington University. (JX88.) On November 20, 1995, WARF submitted Dr. Slatopolsky's assignment agreement to the USPTO for recordation under a cover sheet that indicated *WARF* was the sole assignee. (JX56 at 2.) On March 31, 1996, the USPTO sent WARF a Notice of Recordation of Assignment Document. The Notice of Recordation indicated that WARF — not Washington University — was the sole assignee of Dr. Slatopolsky's interest in the '815 patent. The notice stated in all caps that WARF should "review all information contained on this notice" and contact the USPTO "if you should find any errors." WARF did not submit any correction in response to the Notice. (JX55 at 11.) WARF's

did not learn about the '815 patent's listing in the Orange Book and assertion in litigation until Hospira served a third-party subpoena on Washington University. (Trial Tr. 220:13-222:15 (Dr. Cleare); Trial Tr. 400:8-11, 418:9-22, 433:9-15, 437:14-21 (Mr. Surber).)

Orange Book of the manufacturers' intent to seek FDA approval for a generic form of the corresponding drug. The patent owners may then file suit. (Trial Tr. 838:19-839:4 (Mr. Lentz).) Because of the incorrect assignment records showing WARF as the sole owner of the '815 patent, these manufacturers would not have known that Washington University had an interest in the '815 patent, and would have failed to send the required notifications to Washington University. (Trial Tr. 420:8-19 (Mr. Surber); Trial Tr. 220:13-222:15 (Dr. Cleare).) Moreover, when WARF initiated litigation against the generic manufacturers before this Court, WARF falsely asserted in several of those complaints that WARF alone was the sole assignee of the '815 patent. (See, e.g., JX63 at ¶ 8; see also JX58 at ¶ 11; JX59 at ¶ 9; JX64 at ¶ 16.)

163. As a result, Washington University did not receive notification from generic drug manufacturers about their intention to make a generic form of Zemplar. This prevented Washington University from learning that the '815 patent had been repeatedly asserted in litigation to block generic competition for Zemplar – events that clearly showed that the '815

recordation of false patent assignment information with the USPTO served to keep Washington University in the dark about WARF and Abbott's assertion of the '815 patent in ANDA litigation against generics because Washington University never received any Paragraph IV certifications or any other notice relating to those actions before being served with the Hospira subpoena. (Trial Tr. 220:13-222:15 (Dr. Cleare); Trial Tr. 420:1-19 (Mr. Surber).)

patent was anything but "ancillary" and worth far more than the *de minimis* relative value that WARF continued to use to calculate Washington University's annual royalty share under the IIA. (Trial Tr. 418:9-22, 420:8-19, 433:9-15 (Mr. Surber); Trial Tr. 220:13-222:15 (Dr. Cleare).)

- 164. Notably, in connection with Abbott and WARF's patent infringement lawsuit against Hospira relating to the '815 patent, when Hospira had served a document subpoena on Dr. Slatopolsky in his personal capacity, WARF's counsel in the Hospira litigation contacted Dr. Slatopolsky directly without notifying Washington University's General Counsel's office.

 WARF's counsel responded to the subpoena on Dr. Slatopolsky's behalf, again without contacting Dr. Slatopolsky's employer, Washington University, even though the matter involved issues that related to Dr. Slatopolsky's work for Washington University and that were plainly of significant interest to Washington University under the IIA. (JX359 at 1, 65-78; JX363.)
- 165. All these events including WARF's recordation of false patent assignment information with the USPTO, WARF's concealment of its conclusion that the '815 patent was a blocking patent for Zemplar, Abbott and WARF's decision to list the '815 patent in the Orange Book, and WARF's false patent ownership assertions and its decision to conceal from Washington University that WARF had asserted the '815 patent in litigation against generic Zemplar manufacturers only underscore the lengths to which WARF went to keep Washington University in the dark as to the '815 patent's true relative value.

I. Washington University Receives A Subpoena Relating to WARF and Abbott's Assertion of the '815 Patent in Litigation

Abbott and WARF's patent infringement lawsuit on the '815 patent. The subpoena initiated a cascade of events that alerted Washington University to WARF's misconduct. (JX356; JX358; Trial Tr. 437:14-21 (Mr. Surber).) The subpoena sought documents relating to Washington

University's research on Zemplar, the '815 patent, and Dr. Slatopolsky. (JX358 at 8-10; Trial Tr. 415:12-21 (Mr. Surber).) In compiling responsive documents, Washington University revisited the IIA and WARF's April 4, 2001 letter. (*See* JX174-180; JX356-361; Trial Tr. 415:12-21 (Mr. Surber).) Further investigation triggered by the subpoena suggested that the relative value WARF had assigned to the '815 patent for purposes of allocating royalties to Washington University may have been improper, depending on the identities of the WARF-owned patents included in the Abbott portfolio, and that the '815 patent may have been worth far more than the virtually negligible relative value WARF had assigned to it. (*See* JX174-177; JX179-180; JX356-358; JX360 at 1; JX482-483; Trial Tr. 415:22-416:22 (Mr. Surber).)

- 167. As a result of its investigation triggered by the Hospira subpoena, Washington University discovered that, by late 2011, the '815 patent had been listed in the Orange Book as a patent covering Zemplar. (Trial Tr. 417:14-418:8 (Mr. Surber).) Washington University further discovered as a result of its investigation that WARF had asserted the '815 patent in litigation against generic manufacturers to block generic competition for Zemplar. (Trial Tr. 418:9-22 (Mr. Surber).) Washington University also discovered as a result of its investigation that WARF had recorded false patent assignment information with the USPTO. (Trial Tr. 420:1-19 (Mr. Surber).)
- Zemplar lawsuits that confirmed the '815 patent's substantial value because WARF had recorded false patent assignment information in the USPTO showing WARF to be the sole owner of the '815 patent and had misrepresented its sole ownership in complaints in those actions. (Trial Tr. 417:7-13, 420:8-19, 437:14-21 (Mr. Surber); JX367 at 4; JX482 at 2; JX58-59; JX64.) Had Washington University not received the Hospira subpoena, Washington University would likely

have remained unaware of WARF's improper valuation of the '815 patent. (Trial Tr. 417:7-13, 420:8-19, 437:14-21 (Mr. Surber); Trial Tr. 220:13-222:15 (Dr. Cleare).)

J. Washington University Repeatedly Requests Information from WARF About Its Relative Valuation, But WARF Stonewalls

- requesting, asking for more information about WARF's relative valuation process, and asking WARF to revisit its relative value assignment to the '815 patent in light of WARF's assertion of the '815 patent to block generic competition for Zemplar. (JX195.) Washington University wrote, "You have asked us for a specific proposal to address the valuation issue. We would like to oblige, but to do so responsibly, we will need information that only WARF possesses. (JX195.) Washington University then requested information relating to the '815 patent. Over the ensuing 11 months, Washington University repeatedly asked WARF for information that only WARF possessed regarding the relative value of the '815 patent compared to the other patents in the Abbott portfolio, including importantly the identities of the patents included in the Abbott portfolio, the relative values assigned to those patents and two WARF-owned patents in the Orange Book that protected Zemplar; whether WARF had changed any Inter-Institutional Agreement valuations since its 2001 letter; and WARF's quarterly revenues under the Abbott License. (See JX196-198; JX201; JX204; JX421; Trial Tr. 426:4-432:24 (Mr. Surber).)
- 170. WARF refused to respond meaningfully to Washington University's requests prior to initiation of this lawsuit (which finally gave Washington University access to WARF's internal documents through civil discovery, including importantly the 1998 Abbott License and the identities of the WARF-owned patents licensed along with the '815 patent to Abbott). (Trial Tr. 426:4-432:24 (Mr. Surber).) WARF refused to provide even basic information, such as the identities of the other patents in the Abbott License portfolio, that was needed for Washington

University to evaluate WARF's assertions about the relative value of the '815 patent compared to the WARF-owned patents in the Abbott portfolio. (*See* JX196-198; JX201; Trial Tr. 426:4-432:24 (Mr. Surber); Trial Tr. 989:12-990:10 (Dr. Severson).)

171. In a February 7, 2013 letter to Washington University, WARF took the position that all method of treatment patents, including the '815 patent, were "meaningless and largely irrelevant." (JX197 at 1.) WARF stated, "It is the compound patent that is the gatekeeper patent; without a license to it, the other patents directed to methods of using paricalcitol are meaningless and largely irrelevant." (JX197 at 1.) Unbeknown to Washington University at the time, WARF's position directly conflicted with WARF's allocation of 35% relative value to WARF's '925 patented treatment method in the Zemplar IDM, which WARF concealed from Washington University by asserting that it had assigned 70% relative value to WARF's "compounds patents." (Trial Tr. 992:6-993:23 (Dr. Severson).) WARF's position also directly conflicted with WARF's allocation of 29% value to WARF's multiple sclerosis treatment patent in the Multiple Sclerosis IDM, which WARF concealed from Washington University by asserting that it had a "policy" of assigning equal value to all Ancillary Patents regardless of whether they were "actually currently being used." (Trial Tr. 993:24-999:9 (Dr. Severson).) WARF's position also conflicted with WARF's knowledge of the importance of the '815 patent study in securing FDA approval for Zemplar (JX52 at 6-7), WARF's previous representations to Abbott about that the '815 patent "directly support[ed]" Zemplar (JX47 at 1), WARF's assertion that it had licensed the '815 patent exclusively to Abbott (JX426 at 109:6-14), Abbott's listing of the '815 patent in the Orange Book (JX415), WARF and Abbott's assertion of the '815 patent in litigation (e.g., JX63), and WARF's knowledge that the '815 patent substantially contributed to Zemplar's commercial success. (JX84 ¶ 66; JX87 at 1.)

- 172. Even after Washington University raised its concerns about the fair relative value of the '815 patent with WARF, WARF continued to file lawsuits asserting the patent, including the *Sun Pharmaceutical* and *Dr. Reddy's* cases, without notifying Washington University. (JX60; JX65; JX200.)
- April 9, 2013, while the parties continued their pre-litigation discussions. (D.I. 154-1, Ex. 1, Uncontested Fact No. 32; JX199 Trial Tr. 430:22-432:24 (Mr. Surber).) The Standstill Agreement provided, among other things, that "[t]he running of all potentially applicable statutes of limitation, repose, and laches relating to any claim concerning the IIA or the '815 patent is hereby tolled effective as of the Effective Date, and through the duration of the Standstill Period or such later date as one Party shall initiate any such action or proceeding." (JX199 at 1.) In other words, the Standstill Agreement tolled "any claim" concerning the IIA or the '815 patent effective as of April 9, 2013. (D.I. 154-1, Ex. 1, Uncontested Fact No. 32 (emphasis added).)
- University with documents responsive to Washington University's requests, including the identities of the WARF-owned patents included in the Abbott portfolio. (JX202; Trial Tr. 431:11-24 (Mr. Surber).) WARF insisted in advance that only a small group of Washington University personnel be permitted to view the documents under strict confidentiality obligations. (Trial Tr. 432:1-16 (Mr. Surber).) When WARF finally produced the documents a few weeks later, however, it became clear that WARF's promise, and its insistence on confidentiality, had been a charade. (JX203; Trial Tr. 432:1-16 (Mr. Surber).) The purportedly responsive and sensitive materials consisted of copies of WARF's royalty payment letters to Washington University and other documents that WARF and Washington University had already exchanged

years ago, before this dispute arose. (JX204; Trial Tr. 432:1-16 (Mr. Surber).) WARF continued to refuse to allow Washington University to learn the identities of the WARF-owned patents in the Abbott portfolio, again stymying Washington University's efforts to evaluate WARF's assertions about the relative value of the '815 patent. (Trial Tr. 432:1-24(Mr. Surber).)

- K. WARF Takes Positions in This Ligation Contrary to Positions It Took Before This Court in the *Hospira* litigation
- 175. As explained in the sections that follow, WARF's assertions to explain or defend its misconduct or minimize its damages exposure in this litigation are in direct conflict with WARF's prior admissions, testimony, and positions before this Court in the lawsuits that WARF and Abbott brought to block generic competition for Zemplar.
 - 1. WARF Attempts to Repudiate Its Prior Admissions That the '815 Patent Was Exclusively Licensed to Abbott Under the 1998 Abbott License
- 176. Before Washington University initiated this lawsuit against WARF, WARF consistently treated the '815 patent as exclusively licensed to Abbott under the terms of the 1998 Abbott License. (*See, e.g.*, JX410; JX70 at 1; JX72 at 1; JX73 at 1; JX58 at ¶ 11; JX59 at ¶ 9; JX63 at ¶ 8; JX64 at ¶ 16; JX85, FOF ¶ 1.) In a 2010 email that WARF sent to Washington University, WARF stated "This patent is licensed exclusively to Abbott Labs as part of a package of patents from WARF around the drug Zemplar." (JX410 at 2.) The only "package of patents" that WARF licensed to Abbott that included the '815 patent was the 1998 Abbott License. (JX410 at 2; Trial Tr. 620:17-621:18 (Mr. Thomas).) WARF represented in complaints filed in this Court against Aurobindo, Agila, Sandoz, Banner, Dr. Reddy, and Hikma that Abbott was the exclusive licensee of the '815 patent. (JX58 ¶ 9; JX59 ¶ 9; JX64 ¶ 16; JX65 ¶ 14; JX66 ¶ 18; JX416 ¶ 11.)

WARF also represented in its

Proposed Findings of Fact and Conclusions of Law in the *Hospira* litigation, filed under seal in this Court, that Abbott was the exclusive licensee of the '815 patent. (JX85, FOF ¶¶ 1, 53.)

- unambiguously testified for WARF that the 1998 Abbott License conveyed an exclusive license to the '815 patent to Abbott. (JX426 at 109:6-14 (Mr. Stoveken Rule 30(b)(6) testimony).) Mr. Stoveken, speaking for WARF, testified that "it's plaintiff's position that WARF has granted Abbott an exclusive license to ancillary patents that relate to methods of treatment" in the 1998 Abbott License, such as the '815 patent. (JX426 at 109:6-14.) Mr. Stoveken repeatedly asserted that the '815 patent did not fall within the Nonexclusive License provision, and that WARF had granted an exclusive license to Abbott under the 1998 Abbott License. (JX426 at 98:6-100:11, 102:2-14, 105:7-109:14; *see also* Trial Tr. 515:10-518:1 (Mr. Stoveken); D.I. 163-9, Ex. I at 45:17-48:9 (Mr. Stoveken).)
- 178. WARF's sworn admissions about the exclusive nature of the license to Abbott, however, created a dilemma for WARF in this current lawsuit because WARF assigned greater value to exclusively-licensed patents in the context of the Zemplar IDM. (JX12 at 11.) In this litigation, therefore, WARF has tried to repudiate its prior admissions by taking the position that the '815 patent was non-exclusively licensed to Abbott under the 1998 Abbott License. (*See*, *e.g.*, JX466 at 2-4.) In a sworn interrogatory response in this lawsuit, for example, WARF asserted that "[t]he '815 patent was licensed non-exclusively to Abbott Laboratories via Agreement No. 98-0141, effective July 28, 1998," (JX466 at 3), contrary to WARF's representations to Hospira. (JX426 at 109:6-14 (Mr. Stoveken Rule 30(b)(6) testimony).)
 - 179. WARF's purported repudiations of its prior sworn testimony in the *Hospira*

litigation does not square with the language of the 1998 Abbott License. WARF argues that because the '815 patent was listed among the "Ancillary Patents" in Appendix C of the 1998 Abbott License, that the '815 patent therefore fell within the Nonexclusive License Provision. But the Nonexclusive License Provision refers to both "Licensed Patents" in Appendix B and "Ancillary Patents" in Appendix C, and by its plain terms only granted non-exclusive rights for Abbott "to practice *Processes* of Licensed Patents and Ancillary Patents and to make and use Ancillary Compounds, *but only for the purpose of making the Compound or Products.*" (JX8 at § 2(A)(ii).) Because the '815 patent claims a *method* of using Zemplar, not a *process* of making Zemplar, it does not fall within the Nonexclusive License Provision of the 1998 Abbott License. (*See, e.g.*; Ex. 4 at 14, claim 1; Trial Tr. 1007:7-1008:1 (Dr. Severson) (admitting that "Processes" excluded treatment method patents); Trial Tr. 329:8-332:3 (Dr. Cleare).)

- litigation also does not square with the '815 patent's central importance to Zemplar, including the fact that it covers the approved use of Zemplar and has the ability to block generic competition for Zemplar. A reasonable licensee in Abbott's position would have expected to receive an exclusive license to the '815 patent in order to maintain Zemplar's market exclusivity. (Trial Tr. 329:8-332:3 (Dr. Cleare).) Indeed, Abbott took an exclusive license to the '925 patent, which also covers the approved use of Zemplar, and WARF and Abbott currently consider the '815 license to be exclusive in the United States and Spain. (*See* Trial Tr. 253:19-24 (Dr. Cleare); Trial Tr. 891:20-24 (Mr. Lentz); JX466 at 3.)
- 181. Nevertheless, WARF, its witnesses, and its experts relied on WARF's repudiation of its prior position, whenever possible, to disparage the '815 patent and attempt to minimize WARF's damages exposure in this lawsuit. (*See generally* Trial Tr. 489:4-490:4 (Mr. Stoveken);

Trial Tr. 654:22-655:2, 703:3-15 (Mr. Gulbrandsen); Trial Tr. 795:9-17 (Mr. Lentz); Trial Tr. 1006:3-13 (Dr. Severson); Trial Tr. 1073:6-1075:4 (Ms. Mulhern).) During WARF's closing argument, for example, WARF argued that the '815 patent "didn't have any value" until it was listed in the Orange Book and that the '815 patent was "nonexclusively licensed up until the point that it was asserted in litigation." (Trial Tr. 1177:18-20, 1180:11-14 (WARF's Closing Argument).)

- 182. Mr. Stoveken personally recanted his Rule 30(b)(6) testimony given under oath in the *Hospira* litigation. (Trial Tr. 489:4-490:15 (Mr. Stoveken).) When Washington University took Mr. Stoveken's deposition in this lawsuit, Mr. Stoveken testified that the 1998 Abbott License conveyed a nonexclusive license to the '815 patent because the '815 patent was an "Ancillary Patent" rather than a "Licensed Patent," repudiating his prior sworn testimony in the *Hospira* litigation to the contrary. (*Id.*) Mr. Stoveken admitted that he never submitted a correction to Hospira or the Court, even though he allegedly realized his testimony in the *Hospira* litigation was incorrect a "few days" after he gave it. (Trial Tr. 517:19-518:1 (Mr. Stoveken).) When confronted with the actual language in the 1998 Abbott License that the Nonexclusive License provision covers only "*Processes* of Licensed Patents and Ancillary Patents" (JX8 at 1) Mr. Stoveken could not explain how a method of treatment patent like the '815 patent related to the defined term "Processes." (Trial Tr. 496:16-497:22 (Mr. Stoveken).)
- 183. WARF's experts, Dr. Severson and Mr. Lentz, also testified in this lawsuit that the 1998 Abbott License conveyed a nonexclusive license to the '815 patent because the '815 patent was an "Ancillary Patent" rather than a "Licensed Patent." (Trial Tr. 1006:9-13, 1007:11-14 (Dr. Severson); Trial Tr. 795:9-17, 892:19-23 (Mr. Lentz).) Dr. Severson, however, *admitted* that the defined term "Processes" *excluded* method of treatment patents, like the '815 patent.

(Trial Tr. 1008:3-1009:1 (Dr. Severson).) Mr. Lentz also implicitly conceded that the '815 patented treatment method did not fall within the defined term "Processes." (Trial Tr. 795:18-797:1 (Mr. Lentz).) Both experts agreed that their opinions about the alleged nonexclusive nature of the '815 patent's license to Abbott contradicted Mr. Stoveken's Rule 30(b)(6) testimony in the *Hospira* lawsuit. (Trial Tr. 895:4-12 (Mr. Lentz); Trial Tr. 1012:6-10 (Dr. Severson).) Their opinions also contradicted WARF's and Abbott's treatment of the '815 patent as exclusively licensed and subject to a 7% royalty rate under the terms of the 1998 Abbott License (JX466 at 3), as well as WARF's representation to Washington University in a 2010 email that the '815 patent was "licensed exclusively to Abbott Labs as part of a package of patents from WARF around the drug Zemplar." (JX410 at 2.)⁷

2. WARF Attempts to Repudiate Its Prior Testimony That Zemplar Practices the '815 Patent Claims

184. WARF has also attempted to repudiate its prior sworn admissions in the *Hospira* lawsuit that Zemplar practices the '815 patent and is infringed by generic Zemplar – a fact of

WARF has argued in this lawsuit that its purported attempt to license the '815 patent to Tetrionics and Quatrx showed that WARF did not consider the '815 patent to be exclusively licensed to Abbott in 1998. (See JX16; JX17.) But neither license supports WARF's assertion. In those licenses, WARF granted those companies only the right to "make and use" a single Vitamin D3 compound — not paricalcitol, which is a Vitamin D2 compound. (JX16 § 2(A)(i), Appendix A at C; JX17 §§ 1(D), 2(A)(ii).) WARF then granted Tetrionics non-exclusive rights to practice "Processes of . . . Ancillary Patents . . . only for the purpose of making" the licensed D3 compound. (JX16 § 2(A)(i).) Because the '815 patent relates only to treatment methods for Vitamin D2 compounds, and does not disclose any "Processes" for making Vitamin D3 compounds, these licenses did not convey any rights to the '815 patent at all. WARF recognized this point when it wrote a letter to Quatrx, pointing out that it had "inadvertently included" the '815 patent in the license agreement, and proposed an amendment to remove it. (JX208.) Similarly, WARF recognized in the Tetrionics Income Division Memo ("the Tetrionics IDM") that the '815 patent had been inadvertently included because WARF assigned a 0% relative value to that patent. (See JX16 at 31.) The only thing that the Tetrionics License proves is that WARF did not, as it claimed, "always" assign equal value to the "Ancillary Patents" regardless of their use, as WARF assigned no relative value to the '815 patent after recognizing that it did not contribute to the development or commercialization of the licensed Vitamin D3 compound.

obvious significance to the value of the '815 patent. (JX85, FOF ¶ 58; Trial Tr. 224:21-225:7 (Dr. Cleare); Trial Tr. 827:13-18 (Mr. Lentz); Trial Tr. 953:23-954:3, 981:17-21 (Dr. Severson).)

185. In WARF's pretrial pleadings submitted under seal in the *Hospira* lawsuit, WARF asserted that using Zemplar in accordance with its FDA approved label results in the infringement of each and every claim limitation of claim 4 of the '815 patent. (JX85, FOF ¶¶ 50-54; 506-510.) This position is consistent with the positions taken by WARF's Licensing Manager in 1996, 1998, and 2008 that the '815 patent provides "additional protection" to Zemplar, "directly supports" Zemplar, and is "exactly the application and population that Abbott targets and sells Zemplar for" because "SHPT = renal osteodystrophy." (JX42 at 1; JX47 at 1; JX50 at 1.) As stated above (see supra ¶¶ 75-77), when WARF wrote to Abbott in June 1998 that the '815 patent "directly supports" Zemplar, the FDA had already rejected the "renal osteodystrophy" indication for Zemplar that was directly recited in the '815 patent's claims. (JX47 at 1.) Nevertheless, as WARF and Abbott explained in their pretrial pleadings in the Hospira litigation, Abbott decided not to submit additional studies requested by the FDA to obtain a "renal osteodystrophy" indication "because (1) even without such data, treating physicians recognized the beneficial effect of reducing elevated parathyroid hormone levels in treating renal osteodystrophy because secondary hyperparathyroidism is encompassed by the broad term; and (2) AbbVie did not want to delay approval of Zemplar in order to conduct such studies." (JX85, FOF ¶ 71.) WARF and Abbott supported those positions with expert reports from medical professionals and board-certified internists with subspecialties in nephrology, like Dr. Sprague. (See id. ¶ 72; see also Trial Tr. 861:17-864:23 (Mr. Lentz); JX82 ¶¶ 56-57.) As WARF and Abbott explained it, Abbott recognized that even without the FDA's formal approval of an RO indication on Zemplar's label, "[t]he FDA-approved label for Zemplar demonstrates

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that Zemplar is safe and effective for the treatment of renal osteodystrophy while avoiding hyperphosphatemia as claimed in the '815 patent." (JX85, FOF ¶ 72.) As WARF's tech transfer expert, Dr. Severson, admitted, WARF and Abbott's statements in the *Hospira* lawsuit indicate that "Abbott decided not to pursue the renal osteodystrophy indication at the time *because it knew treating physicians would recognize that they could use Zemplar to treat RO*" — *i.e.*, the indication recited in the '815 patent. (Trial Tr. 1027:4-9 (Dr. Severson) (emphasis added).)

186. In this litigation, however, WARF has argued — contrary to the evidence — that WARF had no reason to believe in 1998 that Zemplar practiced the '815 patent because the FDA in 1998 had rejected Abbott's request for a renal osteodystrophy (RO) indication (the indication claimed in the '815 patent), and had approved Zemplar only for the treatment of secondary hyperparathyroidism (SHPT). WARF's patent licensing expert (Mr. Lentz) and tech transfer expert (Dr. Severson) both testified that the FDA's rejection in April 1998 of an RO indication on Zemplar's label allegedly showed that the '815 patent did not claim the approved use of Zemplar and therefore lacked relevance and value with respect to Zemplar. (Trial Tr. 795:14-796:1, 819:3-19 (Mr. Lentz); Trial Tr. 953:23-954:3 (Dr. Severson).) But neither expert had considered WARF's and Abbott's litigation papers or expert reports from the *Hospira* litigation explaining that physicians as of 1998 would have understood the umbrella term "SHPT" to encompass "RO" and that using Zemplar to treat SHPT would have necessarily treated RO, as well. (Trial Tr. 861:8-867:13 (Mr. Lentz); Trial Tr. 1019:16-1022:1, 1026:2-1027:24 (Dr. Severson).) As WARF and Abbott explained in sealed court papers filed in the District of Delaware, Abbott knew at the time of FDA approval in April 1998 that even without the FDA's formal approval of an RO indication on Zemplar's label, "[t]he FDA-approved label for Zemplar demonstrates that Zemplar is safe and effective for the treatment of renal osteodystrophy while

avoiding hyperphosphatemia as claimed in the '815 patent." (JX85, FOF ¶ 72.)

- 187. Dr. Severson, for example, testified that WARF's paltry relative value assignment to the '815 patent was fair because "because the claim of the '815 patent to renal osteodystrophy did not cover the approved indication of Zemplar." (Trial Tr. 953:17-954:3 (Dr. Severson).) Dr. Severson formed that opinion because he "didn't know the relationship between secondary hyperparathyroidism and renal osteodystrophy." (Trial Tr. 1019:24-1020:6 (Dr. Severson).) Dr. Severson admitted he was unable to reconcile his opinion that the "'815 patent lacks substantial value because of the nonequivalence of SHPT and RO with WARF and Abbott's position in the *Hospira* litigation." (Trial Tr. 1027:19-24 (Dr. Severson).) Despite having a Ph.D. in physiology and nearly thirty years of experience in executive tech transfer positions, Dr. Severson admitted that "[he] didn't see the relevance of the '815 patent to Zemplar until [he] learned about it from WARF's files *after [he] signed [his] expert report.*" (Trial Tr. 1027:10-19 (Dr. Severson) (emphasis added).)
- 188. WARF's positions in this lawsuit, therefore, directly contradict the evidence as stated in WARF's prior positions in its litigation against Hospira in this Court.
 - 3. WARF Attempts to Repudiate Its Prior Admissions in This Court That the '815 Patent Contributed to Zemplar's Commercial Success
- 189. WARF has also attempted to repudiate its prior admissions in the *Hospira* lawsuit that the '815 patent substantially contributed to Zemplar's commercial success, arguing in this litigation instead that the '815 patent was "meaningless and largely irrelevant." (JX85, FOF ¶ 334; JX197; Trial Tr. 842:2-10 (Mr. Lentz); Trial Tr. 427:19-428:4 (Mr. Surber).)
- 190. In the *Hospira* litigation, WARF served a rebuttal expert report dated July 1, 2013 prepared by Dr. Robert L. Vigil a WARF-hired economist. (JX84 at ¶¶ 1, 4.) In that report, Dr. Vigil concluded that Zemplar had enjoyed immense commercial success, and that "this

success has been due, in large part, to the benefits, merits, and advantages of the inventions described in the asserted claims of the '815." (JX84 at ¶ 3.) Dr. Vigil's opinions were based on a variety of evidence, including numerous Abbott marketing documents in which Abbott touted the benefits of Zemplar as established in the '815 patent study and in third-party news articles. (JX84 at ¶ 3; Trial Tr. 533:7-539:18 (Mr. Thomas).) Dr. Vigil also rejected the opinion of Hospira's expert, Dr. Addanki, that the '815 patent made no additional contribution beyond the '925 patent, noting that the '925 patent (unlike the '815 patent) contained no disclosure about paricalcitol's minimal impact on blood phosphorous levels. (JX84 ¶¶ 51-52.)

- 191. Even though Dr. Vigil's opinions about the value of the '815 patent and, indeed, the superiority of the '815 patent over the '925 patent would have been informative to Washington University of the value of the '815 patent, WARF did not produce copies to Washington University (except in civil discovery in this litigation). (Trial Tr. 228:22-229:21 (Dr. Cleare); Trial Tr. 541:18-22 (Mr. Thomas).) As of the date of Dr. Vigil's rebuttal expert report, WARF and Washington University were already engaged in pre-litigation discussions regarding the value of the '815 patent. (*See, e.g.*, JX204.) The contents of Dr. Vigil's report directly contradicted WARF's representation in its February 7, 2013 letter to Washington University that all method of treatment patents, including '815 patent, were "meaningless and largely irrelevant" compared to WARF's compound patent. (JX84 at 13-30; JX197.)
- 192. WARF made similar admissions in its pretrial pleadings in the *Hospira* litigation. WARF stated, for example, that "Zemplar is successful because of its wider therapeutic window, which results from, inter alia, paricalcitol's ability to be used in methods of treatment while avoiding hyperphosphatemia. It is this wider therapeutic window that leads physicians to use Zemplar with patients. *Paricalcitol's ability to be used in a method of treating renal*

osteodystrophy while avoiding hyperphosphatemia drives sales and prescriptions. Therefore, there is a nexus between claim 4 of the '815 patent and the commercial success of Zemplar." (JX85, FOF ¶ 334) (emphasis added.)

- 193. WARF has taken the opposite position with Washington University in this lawsuit. (*E.g.*, JX197 at 1.) At trial, during WARF's direct examination of its patent licensing expert, Mr. Lentz, WARF asked whether Hospira's rebuttal expert report to Dr. Vigil's commercial success analysis "support[ed] [Mr. Lentz's] opinion that the '497 dominating compound patent, in view of that, it's only minimal value to the '815 commercial success report." (Trial Tr. 911:12-16 (Mr. Lentz).) Mr. Lentz asserted that the '815 patent did not make any "additional contribution to the sales of Zemplar injection over the '925 patent," (Trial Tr. 912:20-913:2 (Mr. Lentz)), even though Dr. Vigil had taken the opposite view in his commercial success report (JX84 ¶ 51-52), and even though Mr. Lentz admitted that the '925 patent contained no disclosure of the '815 patent's key teachings about how to administer paricalcitol while minimizing serum phosphorous levels. (Trial Tr. 876:20-877:15, 879:8-14 (Mr. Lentz).)
- 194. Ms. Mulhern a WARF damages expert and colleague of Dr. Vigil from the same consulting firm also relied upon the supposed absence of any evidence linking the '815 patented invention to Zemplar's commercial success in the market as a supposed justification for an extremely low damages number. Without considering Dr. Vigil's analysis, Ms. Mulhern provided opinions in this case that the '815 patent provided no incremental benefit over the '497 and '925 patents, even though Dr. Vigil had concluded the opposite in his expert report. (Trial Tr. 1073:6-13, 1087:11-1088:2, 1117:14-1118:5 (Ms. Mulhern).)

III. PROPOSED CONCLUSIONS OF LAW

- A. Breach of Contract and Breach of the Implied Covenant of Good Faith and Fair Dealing
- 195. WARF does not dispute that the IIA is a valid and enforceable contract, that the implied covenant of good faith and fair dealing applies to the IIA, and that Washington University did not breach any provision of the IIA that would excuse WARF's contractual performance. (Proposed FOF ¶¶ 41-44, 60-65.) Therefore, the only disputed issues are whether WARF breached the IIA and/or the implied covenant and, if so, the amount of the resulting damages.
- of that contract and damages flowing reasonably from that breach." *Nw. Motor Car, Inc. v. Pope*, 187 N.W.2d 200, 202 (Wis. 1971). "When interpreting an agreement, the court's objective is to ascertain the true intentions of the parties as expressed by the contractual language." *First Bank & Trust v. Firstar Info. Servs. Corp.*, 276 F.3d 317, 322 (7th Cir. 2001) (applying Wisconsin law) (quotations and citations omitted). When interpreting the terms of the contract, the Court "must reject a construction that renders an unfair or unreasonable result" and "should adopt a construction that will render the contract a rational business instrument so far as reasonably practicable." *Gottsacker v. Monnier*, 697 N.W.2d 436, 442 (Wis. 2005).
- 197. Under Wisconsin law, evidence of "custom and usage is permissible 'to define what is ambiguous or is left indeterminate in a contract, where both parties have knowledge of the custom or are so situated that such knowledge may be presumed." *Dieck v. Oconto Co.*, 180 N.W. 932, 935 (Wis. 1921) (citation omitted); *Fid. Nat'l Title Ins. Co. v. Intercounty Nat'l Title*

⁸ Washington University's contract claims arise under state law. *See Volt Info. Scis., Inc. v. Bd. of Trs. of Leland Stanford Junior Univ.*, 489 U.S. 468, 474 (1989). Specifically, Wisconsin law applies to the parties' IIA pursuant to a Wisconsin choice-of-law provision. (*See JX1* § 12.)

Ins. Co., No. 00 C 5658, 2001 U.S. Dist. LEXIS 9626, at *8 (N.D. Ill. July 9, 2001) ("[E]xperts are allowed to testify about the customs and standards of an industry when that testimony is used to explain the terms of ambiguous contracts or to supplement the terms of a contract.").

198. The Court may therefore consider extrinsic evidence of customary practices in the university tech transfer industry to "assist[] in the construction of [any] ambiguous [or indefinite] terms," including the Cooperation Clause, Mutual Benefit Clause, and Relative Value Clause. *See Dieck*, 180 N.W. at 935. As Dr. Cleare demonstrated, the relevant professional standards governing the level of trust and cooperation between senior parties and junior parties to an IIA, and the assignment of relative value were prevalent in the industry and known to the parties at the time of the IIA. (*See* Trial Tr. 178:12-182:15, 184:22-185:19 (Dr. Cleare).) WARF's own tech transfer expert acknowledged that WARF's professional obligations included duties of fairness, collegiality, and honest within the "senior party – junior party" framework. (Trial Tr. 982:4-12, 983:7-18, 990:16-20, 1000:6-1001:22, 1009:2-4, 1028:4-1029:24 (Dr. Severson).)

Wash. Univ. v. Wis. Alumni Research Found., 703 F. App'x 106, 108 (3d Cir. 2017). "Good faith performance or enforcement of a contract emphasizes faithfulness to an agreed common purpose and consistency with the justified expectations of the other party; it excludes a variety of types of conduct characterized as involving 'bad faith." Id. (citation omitted). "Even where all of the written terms of a contract have been fulfilled, a party may be liable for breaching the covenant of good faith and fair dealing." Id. "However, one cannot establish a claim for breach of this covenant when the acts constituting the breach are authorized by the contract. The rule was not intended to undo express terms of a contract, but 'obligations under those terms must be performed subject to that implied covenant." Id. at 109 (citation omitted).

200. Wisconsin law defines what good faith means in the negative:

Subterfuges and evasions violate the obligation of good faith in performance even though the actor believes his conduct to be justified. But the obligation goes further: bad faith may be overt or may consist of inaction, and fair dealing may require more than honesty. A complete catalogue of types of bad faith is impossible, but the following types are among those which have been recognized in judicial decisions: evasion of the spirit of the bargain, lack of diligence and slacking off, willful rendering of imperfect performance, abuse of a power to specify terms, and interference with or failure to cooperate in the other party's performance.

Designer Direct v. Deforest Redevelopment Auth., 313 F.3d 1036, 1046-47 (7th Cir. 2002) (citation omitted).

- 201. In *Designer Direct*, the Seventh Circuit affirmed the district court's finding of breach of the implied covenant of good faith and fair dealing under Wisconsin law. 313 F.3d at 1046-47. The Seventh Circuit agreed with the district court's determination that the parties' "contract was founded on ongoing cooperation" and that the defendant's actions "violated the standards of fairness and reasonableness" when they "undermine[d] the communication, [and] the cooperation essential to successful completion of the contract." *Id.* at 1047.
- 202. Likewise, in *Market Street Associates Limited Partnership v. Frey*, 941 F.2d 588, 597 (7th Cir. 1991), the Seventh Circuit held that "deliberately [taking] advantage of your contracting partner's mistake during the performance stage (for we are not talking about taking advantage of superior knowledge at the formation stage) is a breach of good faith." In that case, Market Street Associates had asked its lessor to engage in financing negotiations without disclosing that Paragraph 34 of their agreement allowed Market Street Associates to buy back the leased property for less than market value if the negotiations failed. 941 F.2d at 591. When the lessor declined to engage in financing negotiations, Market Street Associates attempted to exercise its "buy back" rights. *Id.* The district court ruled on summary judgment that "by failing in its correspondence with the pension trust to mention paragraph 34 of the lease, Market Street

Associates had prevented the negotiations over financing that are a condition precedent to the lessee's exercise of the purchase option from taking place." *Id.* at 592. The Seventh Circuit agreed that if the lessor *had* made a mistake by failing to read the contract, and Market Street Associates *had* tried to take advantage of that mistake, then the duty of good faith and fair dealing prevented Market Street Associates from exercising its "buy back" rights. *Id.* at 597. The Seventh Circuit reversed and remanded for trial proceedings on those issues. *Id.* at 598.

203. Just as the Court may consider extrinsic evidence of customs and practices in the university tech transfer industry to assist in its construction of any ambiguous or indefinite terms in the IIA, so too may the Court use that evidence when evaluating Washington University's implied covenant claim, including whether WARF breached the implied covenant by acting in a manner inconsistent with Washington University's reasonable expectations. Wash. Univ., 703 F. App'x at 108 (good faith performance emphasizes "consistency with the justified expectations of the other party"); Gilson v. Rainin Instrument, LLC, No. 04-C-852-S, 2005 U.S. Dist. LEXIS 16825, at *8 (W.D. Wis. Aug. 9, 2005) ("Whether the duty to act in good faith has been met in this case should be determined by deciding what the contractual expectations of the parties were."). Because the duty of good faith and fair dealing incorporates commercially reasonable standards of dealing, evidence of industry custom and practice is relevant and admissible to help define what a reasonable person would have expected from his or her contractual partner, and therefore to help determine whether a contractual partner breached the duty of good faith and fair dealing. Gilson, 2005 U.S. Dist. LEXIS 16825, at *8-9 ("This duty of good faith means honesty in fact and the observance of reasonable commercial standards of fair dealing in the trade."); see also U.S. Bank Nat'l Ass'n v. PHL Variable Life Ins. Co., 112 F. Supp. 3d 122, 135-36 (S.D.N.Y. 2015) ("Industry practices and standards are relevant to [an implied covenant claim] insofar as

they may inform what a reasonable policyholder would expect under a contract.").

1. WARF Breached the IIA and the Implied Covenant of Good Faith and Fair Dealing

204. WARF breached the IIA and deprived Washington University of the benefits of the parties' bargain by (among other things): (1) failing to assign a fair relative value to the '815 patent in light of all the circumstances, (2) engaging in self-dealing by applying an unfair double standard to the '815 patent and over-allocating relative value that WARF assigned to its solely owned patents at the expense of the parties' co-owned '815 patent, (3) concealing and misrepresenting information that Washington University needed to detect WARF's breach and challenge WARF's improper relative valuation, and (4) making annual payments to Washington University that did not reflect the fair relative value of the parties' co-owned '815 patent.

a. WARF Failed to Assign a Fair Value in Light of All the Circumstances

- 205. As explained above (*see* Proposed FOF ¶¶ 41-44), the Relative Value Clause of the IIA required WARF to assign a fair value to the '815 patent in light of all the circumstances. (JX1 at § 3(A)(iii).) This interpretation is required by the plain language of the words "value" and "relative value," which invoke an objective standard for determining patent value in light of all the circumstances. (*See id.* ¶ 44 n.4.) Any other interpretation would mean that WARF could have assigned an arbitrary "value" to the '815 patent, even a 0% value, with impunity. That result would contradict the plain language of the Relative Value Clause, the restrictions imposed on WARF under the Mutual Benefit Clause, and the undisputed extrinsic evidence that WARF had an obligation to assign a fair value to the '815 patent in light of all known information about the value of the '815 patent. (*See id.* ¶¶ 41-44.)
- 206. The duty of good faith and fair dealing also "require[d] WARF to exercise its authority to assign relative values fairly and in good faith." (D.I. 130 at 21.) *See also Wash*.

Univ., 703 F. App'x at 109 ("We agree with the District Court's conclusion that the Agreement created an obligation of good faith and fair dealing which governed WARF's assessment of the amount of royalties owed to the University."). WARF could therefore not assign a relative value to the '815 patent in a manner that frustrated Washington University's justified expectations.

See Gilson, 2005 U.S. Dist. LEXIS 16825, at *7. As WARF's own tech transfer expert admitted, Washington University reasonably expected that WARF would assign a fair value to the parties' co-owned '815 patent, using all information in its possession about that patent's value. (Trial Tr. 982:4-7, 983:7-14 (Dr. Severson).)

207. Even though the IIA and the implied covenant prohibited WARF from ignoring information about the '815 patent's value and assigning it less than a fair relative value, that is exactly what WARF did. (Proposed FOF ¶¶ 96-118.) WARF freely admits that it did not perform any patent-specific evaluation of the '815 patent when it assigned it negligible relative value. (See id. ¶ 97.) WARF's long-time Managing Director from 1997 to 2016, Mr. Gulbrandsen, testified that WARF merely assigned 70% of the value to the Licensed Patents listed in Appendix B of the 1998 Abbott License (i.e., the WARF-owned '497 and '925 patents), and then assigned equal shares of the remaining 30% to the 30 Ancillary Patents in Appendix C of that license, without making any patent-specific valuation decisions aside from those two patent groupings. (See id.) Contrary to WARF's contractual obligations and Washington University's reasonable expectations, WARF ignored information about the value of the '815 patent when it assigned a relative value to the '815 patent (see Proposed FOF ¶¶ 67-95), including that (1) Abbott "knew treating physicians would recognize that they could use Zemplar to treat RO," as claimed in the '815 patent (Trial Tr. 1027:4-9 (Dr. Severson); JX85, FOF ¶ 71) and that (2) WARF knew the '815 patent "directly support[ed]" Zemplar (JX47 at 1).

At the time of WARF's initial valuation, WARF knew that the '815 patent study 208. represented the first "Action" item that Abbott needed to undertake in its "Development Plan" to obtain FDA approval of Zemplar, as stated in the 1993 Abbott License. (See Proposed FOF ¶¶ 67-69.) Because WARF handled all patent prosecution on behalf of the parties, WARF knew that the '815 patent study demonstrated Zemplar's superiority over Calcijex, and that one of its key advantages — that it could be administered in a way to avoid hyperphosphatemia and minimize blood phosphorous levels — represented a novel and nonobvious advance over WARF's '925 patent, which contained no teaching about serum phosphorous levels. (See id. ¶ 22.) When WARF received the FDA's Medical Review of Zemplar shortly before FDA approval, WARF knew that the '815 patent study helped establish Zemplar's "advantages" over Calcijex, including its ability to minimize blood phosphorous levels. (See id. ¶¶ 73-74.) Immediately after the PTO allowed the '815 patent claims, WARF wrote to Abbott that the patent would provide "additional protection" for Zemplar. (See id. ¶¶ 70-72.) Shortly after FDA approval of Zemplar for the treatment of SHPT, WARF wrote to Abbott that the patent "directly supports" Zemplar. (See id. ¶¶ 75-77.) WARF came to this conclusion notwithstanding the FDA's rejection of an RO indication for Zemplar, as recited in the '815 patent claims. (See id.) As Abbott and WARF acknowledged in the *Hospira* litigation, WARF and Abbott knew in April 1998 that because of the equivalence of SHPT and RO, physicians would prescribe Zemplar to treat both conditions, and therefore Abbott decided not to delay Zemplar's approval by submitting the additional studies needed to obtain FDA approval of an RO indication. (See id. ¶ 75.) Finally, according to WARF's sworn testimony in the *Hospira* litigation, WARF knew that Abbott had taken an exclusive license to '815 patent under the 1998 Abbott License effective July 28, 1998, that the patent covered Zemplar's approved use, and that the patent

triggered a 7% "earned royalties" obligation over the life of the patent. (See id. ¶¶ 83-85.)

- 209. WARF knew all this information at the time it assigned negligible 0.968% relative value to the '815 patent in October 16, 1998. (*See* Proposed FOF ¶¶ 98-106.) Despite WARF's actual knowledge of the patent's contributions to the development and commercialization of Zemplar, WARF's contractual commitments under the IIA, and Washington University's reasonable expectations (Trial Tr. 982:4-7, 983:7-14 (Dr. Severson)), WARF performed no patent-specific evaluation of the '815 patent at all. (Trial Tr. 663:16-20 (Mr. Gulbrandsen).) WARF's improper exercise of its "authority" under the Relative Value Clause breached the IIA and the implied covenant, and frustrated Washington University's reasonable expectations that WARF, as the senior party, would fairly allocate and share the cowned patent's royalties with Washington University. (*See* Proposed FOF ¶¶ 96-118.)
- 210. Not surprisingly, WARF's Managing Director, Mr. Gulbrandsen, testified at trial that he believed WARF's approach to assigning relative value under the IIA "worked beautifully" for WARF. (Trial Tr. 711:9-16 (Mr. Gulbrandsen).) The effect of WARF's valuation was to assign 99.032% of the Abbott portfolio's value to WARF's solely-owned patents, even though it is undisputed that the vast majority of them contributed virtually nothing to Zemplar, with only three patents that generated "earned royalties" over the course of Zemplar's protected lifetime: the '497, '925, and '815 patents. (*See* Proposed FOF ¶¶ 102-103, 107-114.)
- 211. WARF had no reasonable economic justification for its 0.968% value assignment to the '815 patent. The '815 patent has certain characteristics that render it one of the most valuable patents in the portfolio licensed in the 1998 Abbott Agreement. (*See id.* ¶¶ 98-114.) Along with the '497 and '925 patents, the '815 patent was the only other patent in the Vitamin D

portfolio licensed to Abbott that generated "earned royalties" under the 1998 Abbott License, covered Zemplar or its approved use, was listed in the Orange Book as reading on the approved indication of Zemplar, and was asserted against generic manufacturers to block generic competition for Zemplar. (*See id.*) WARF represented to the Court in its litigation proceedings against those generic manufacturers that generic Zemplar (paricalcitol) would infringe the '815 patent, that the '815 patent was valid and enforceable, and that the '815 patent contributed to the commercial success of Zemplar. (*See id.* ¶ 175-194.) Finally, of the three Orange Book listed patents licensed under the 1998 Abbott License, the '815 patent has the longest life – conferring an additional 1.55 years of patent exclusivity for Zemplar over the '497 patent and an additional 3.24 years of patent exclusivity for Zemplar over the '925 patent. (*See id.* ¶ 106.)

212. Mr. Gulbrandsen's explanation for WARF's failure to perform a patent-specific valuation analysis was that WARF's "staff was not skilled in that" and it would need to "hire an outside firm" to do that kind of evaluation. (Trial Tr. 663:21-664:6 (Mr. Gulbrandsen).) But this explanation overlooks that Washington University paid WARF a 15% administration fee as consideration for WARF's administration of the Abbott license for the parties' mutual benefit, totaling nearly \$620,000 over the life of the Abbott License. (*See id.* ¶ 33.) WARF can hardly complain that it lacked sufficient resources to conduct a proper valuation of the '815 patent. Moreover, Ms. Kirkpatrick had already concluded at the time of WARF's valuation that the '815 patent "directly support[ed]" Zemplar. (*See id.* ¶ 75-77.) This was not a hasty or uninformed determination. Ms. Kirkpatrick was a WARF Licensing Manager with responsibility for the Abbott portfolio. (*Id.* ¶ 76.) She came to WARF from Abbott. (*Id.*) She performed "a very diligent, tedious review of the entire DeLuca portfolio." (*Id.*) She attended an Abbott launch presentation and training session about Zemplar, which Dr. DeLuca and Mr. Gulbrandsen also

attended. (*Id.*) Her statement to Abbott that the '815 patent "directly support[ed]" Zemplar came less than two months after the FDA rejected an RO indication for Zemplar and Abbott decided not to delay launch by seeking approval of an RO indication because it knew physicians would prescribe Zemplar to treat both SHPT and RO anyway. (*Id.*) Yet WARF turned a blind eye to this information when it arbitrarily assigned the '815 patent a trifling 0.968% value.

- 213. At trial, WARF's technical experts testified that the '815 patent was *actually* worth 0.968% relative value because the '815 patent did not read on the FDA approved use of Zemplar. (See Proposed FOF ¶¶ 184-188.) When those experts signed their reports, however, WARF withheld from them WARF's litigation papers in the *Hospira* lawsuit showing that WARF and Abbott knew as of April 1998 that the '815 patent read on Zemplar based on the equivalence of SHPT and RO. (See id. ¶¶ 186-187.) Dr. Severson admitted that he "didn't see the relevance of the '815 patent to Zemplar until [he] learned about it from WARF's files after [he] signed his expert report," and that he was "unable to reconcile [his] opinion that the '815 patent lacks substantial value because of the nonequivalence of SHPT and RO with WARF and Abbott's position in the *Hospira* litigation." (Trial Tr. 1027:14-24 (Dr. Severson).)
- 214. At trial, WARF's technical experts also testified that the '815 patent was an "Ancillary" patent that WARF licensed nonexclusively to Abbott, and therefore lacked substantial value. (See Proposed FOF ¶¶ 176-183.) WARF's damages expert relied on their testimony to argue that the '815 patent did not generate "earned royalties" until 2012, when the '815 patent spontaneously became exclusively licensed in connection with WARF and Abbott's assertion of the '815 patent in litigation, despite the absence of any written license agreement other than 1998 Abbott License. (See id. ¶¶ 181; JX466 at 3.) WARF's experts admitted that their testimony about the nonexclusive nature of the '815 patent's license under the 1998 Abbott

License contradicted WARF's Rule 30(b)(6) testimony in the *Hospira* litigation and also contradicted the plain language of that license. (Proposed FOF ¶¶ 189-194.) Their testimony also contradicted WARF's representations to Washington University in 2010 that it had licensed the '815 patent exclusively to Abbott "as part of a package of patents from WARF around the drug Zemplar." (JX410 at 2.)

- 215. WARF's experts also testified that the '815 patent did not contribute to Zemplar's commercial success, despite the opinions of WARF's expert, Dr. Vigil, in the Hospira lawsuit that Zemplar's success "has been due, in large part, to the benefits, merits, and advantages of the inventions described in the asserted claims of the '815." (JX84 ¶ 3.) WARF's damages expert in this case, Ms. Mulhern, for example, testified that WARF did not ask her to look at Dr. Vigil's expert report when she wrote her report, even though Dr. Vigil is from the same firm as Ms. Mulhern and the two work out of the same office. (*See* Proposed FOF ¶ 194.)
- 216. WARF has also argued that it did not breach the IIA or the implied covenant of good faith and fair dealing because it assigned relative value "in accordance with WARF's policies," which, WARF implies, was specifically authorized by the IIA. (*See id.* ¶ 115-118.) However, the IIA does not authorize WARF to assign relative values "in accordance with WARF's policies." It says nothing about WARF's policies and merely grants WARF "authority" to assign relative values. (JX1 § 2(A)(iii).) Nor were any valuation policies disclosed during the parties' contract negotiations. (*See* Proposed FOF ¶ 115.) Moreover, WARF did not assign relative value to the '815 patent in accordance with its "policies." WARF's written valuation policy allowed WARF to assign value based on its "disproportionate value . . . in the development and commercialization of" Zemplar. (*See id.* ¶ 116-118.) WARF's relative valuation of the '815 patent, however, ignored that patent's disproportionate

contributions to the development and commercialization of Zemplar, in violation of WARF's obligations under the IIA and Washington University's reasonable expectations. (*See id.* ¶¶ 97-106.)

- 217. If WARF had conducted a proper relative valuation in October 1998, it would have assigned the parties' co-owned '815 patent a 33% relative value *i.e.*, an equal share of the earned royalties generated by the '815, '497, and '925 patents in recognition that the '815 patent was one of only three patents in the 1998 Abbott License that covered the FDA-approved indication of Zemplar, was eligible to be listed in the Orange Book, and was eligible to be asserted in litigation to block generic competition for Zemplar. (*See infra* ¶¶ 242-247.)
 - b. WARF Applied an Unfair Double Standard to the '815 Patent and Engaged in Self-Dealing at Washington University's Expense
- 218. As explained above, the IIA's Mutual Benefit Clause prohibited WARF from engaging in self-dealing, such as by applying an unfair double standard to the '815 patent and by overallocating relative value to WARF's solely-owned patents at the expense of the parties' co-owned '815 patent. (*See* Proposed FOF ¶¶ 30, 37, 52-53, 116-118, 134-135.)
- 219. Inherent in the duties required by the Mutual Benefit Clause, WARF had an obligation not to apply an unfair double standard to WARF's patents as to the parties' co-owned '815 patent, or to engage in self-dealing at the expense of Washington University's share of earned royalties, as WARF's own tech transfer acknowledged. (*See id.* ¶ 30, 37, 52.) Similarly, Washington University had a reasonable expectation, under professional standards in the industry, that WARF would not apply an unfair double standard to the parties' co-owned '815 patent, and would not improperly favor WARF's solely-owned patents when assigning relative value to the portfolio patents. (Trial Tr. 1000:21-1001:8, 1009:2-4 (Dr. Severson).)
 - 220. WARF breached the IIA and implied covenant when it applied an unfair double

standard to the '815 patent and engaged in self-dealing by assigning disproportionate value to WARF-owned patents with virtually no relation to Zemplar. (*See* Proposed FOF ¶¶ 107-118, 134-135.)

- 221. First, WARF did not apply the same valuation standard to the parties' co-owned '815 patent as it applied to its own similarly situated patents. (*See id.* ¶¶ 129-135.) WARF's '925 patent, like the '815 patent, covered the primary indication of Zemplar, was licensed exclusively to Abbott, and generated earned royalties under the 1998 Abbott License. And, in many ways, the '815 patent was even more valuable that the '925 patent because the '815 patent taught (and claimed) how to administer paricalcitol to suppress PTH while avoiding hyperphosphatemia a key teaching that convinced both the FDA and treating physicians of Zemplar's advantages over Calcijex. (*See id.* ¶¶ 103-105.) The '815 patent also had a much longer patent term than the '925 patent. (*See id.* ¶¶ 106.) Yet, WARF assigned the '925 patent 35% relative value, but assigned the '815 patent only 0.968% relative value. (*See id.* ¶¶ 97, 130.)
- 222. WARF's stated justification to Washington University in its April 4, 2001 letter for assigning 0.968% value to the '815 patent was that (1) the '815 patent was an Ancillary Patent, not one of WARF's "compound patents" and (2) WARF had a policy to assign equal value to all Ancillary Patents "regardless of whether or not the patent [was] actually currently being used by the Licensee." (See Proposed FOF ¶ 129-135.) But WARF's multiple sclerosis patent was also an "ancillary" patent. (See id. ¶ 117-118, 134.) Just as the '815 patent read on Zemplar's approved use, so did WARF's multiple sclerosis ancillary patent read on an anticipated multiple sclerosis indication that WARF believed would generate "royalty payments deriving from the Multiple Sclerosis field." (See id. ¶ 117.) Rather than assign its own multiple sclerosis patent a value equal to all other "ancillary" patents "regardless of whether or not the

patent [was] actually currently being used," WARF assigned that multiple sclerosis patent a full 29% relative value to be applied exclusively to any multiple sclerosis revenue from sales of the covered indication. (*See id.* ¶¶ 117.) When WARF assigned relative value to the parties' coowned '815 patent, however, WARF applied a much less favorable standard that ignored the '815 patent's contributions to Abbott's royalty payments from Zemplar's sales on the purported basis it was "ancillary" and not entitled to disproportionate value on that basis. (*See id.* ¶¶ 117-118, 134.)

- 223. If WARF had applied the same standard to the '815 patent as it did to WARF's own Multiple Sclerosis ancillary patent in this analogous valuation context, then WARF should have assigned at minimum a 29% value to the '815 patent. (*See infra* ¶ 251-253.)
- 224. Second, WARF's assignment of 0.968% relative value to the '815 patent was the same value that WARF assigned to *each* of 29 Ancillary Patents that obviously were much less valuable than the '815 patent, such as a patent application for preventing transplant rejection that WARF abandoned in January 1999, only a few months after its October 1998 valuation. (Proposed FOF ¶¶ 107-113, 136.) As Dr. Cleare showed, *and as no WARF witness refuted*, the Ancillary Patent group contained 18 patents that did not relate to making 19-nor Vitamin D compounds like paricalcitol. (*See id.* ¶¶ 107-108.) It contained 6 patents that did not relate to the FDA-approved use of Zemplar. (*See id.* ¶¶ 109-110.) It contained an entirely duplicative patent that served only to dilute the '815 patent's value. (*See id.* ¶ 111.) And it contained 4 patents that Dr. Cleare could not rule out as relevant to making paricalcitol, that would be easy to design around, and where there was no evidence that Abbott benefitted from or relied on those patents in any way. (*See id.* ¶¶ 112-113.)
 - 225. If WARF had not overallocated royalties to the 29 Ancillary Patents solely owned

by WARF that had no substantial value with respect to Zemplar, then WARF would have assigned all 30% of relative value assigned to Ancillary Patents to the parties' co-owned '815 patent, in recognition that only the '815 patent contributed to the development and commercialization of Zemplar. (*See infra* ¶¶ 248-250.)

- c. WARF Concealed and Misrepresented Information Washington University Needed to Detect WARF's Breach
- WARF had a duty under the IIA to "use all reasonable efforts to cooperate" with Washington University with respect to WARF's "licensing" activities relating to the '815 patent, and to administer the 1998 Abbott License for the parties' "mutual benefit." (JX1 §§ 2(A)(iii), 2(B)(ii).) WARF also had a duty under the implied covenant and relevant professional standards to be fair and collegial with Washington University, to keep Washington University reasonably informed about the value of the '815 patent, and to provide honest and accurate information to Washington University about WARF's relative valuation. (*See* Proposed FOF ¶ 28, 30-31, 37, 39; Trial Tr. 982:8-12 (Dr. Severson).) The duty of good faith and fair dealing also imposed on WARF "a duty to be honest to Washington University under the IIA in its dealings under the IIA," as WARF's own tech transfer expert acknowledged. (Trial Tr. 983:7-18 (Dr. Severson).)
- 227. WARF breached the IIA and the implied covenant of good faith and fair dealing by (1) concealing information from Washington University pointing to a much higher valuation for the '815 patent (*see* Proposed FOF ¶¶ 66-95), (2) making numerous, highly material misrepresentations in its April 4, 2001 letter purporting to explain its valuation of the '815 patent relative to the other patents in the portfolio (*see id.* ¶¶ 119-140), and (3) misrepresenting to the USPTO, to this Court, and to generic manufacturers WARF's supposed "sole" ownership of the '815 patent, which kept Washington University from receiving Paragraph IV notices of WARF and Abbott's assertion of the '815 patent in litigation (*see id.* ¶¶ 160-165).

- 228. If WARF had complied with its obligations under the IIA and the implied covenant of good faith and fair dealing, Washington University could have detected WARF's breach and raised a timely challenge to WARF's improper valuation. (*See infra* ¶ 271-290.)
 - d. WARF Failed to Make Annual Payments in Accordance with a Fair Relative Valuation
- 229. Under the IIA's Annual Payment Provision, WARF also had an obligation to make periodic payments to Washington University. (Proposed FOF ¶¶ 54-55.) WARF breached the agreement each year it made royalty payments to Washington University in amounts less than required under a fair relative value of the '815 patent. (*See infra* ¶¶ 293-302.)
- 230. As WARF's damages expert admitted, WARF calculated the amount it remitted to Washington University each year. (*See id.* ¶¶ 55.) Specifically, WARF took the topline revenue number received from Abbott under the 1998 Abbott License. (*See id.*) WARF then looked at the relative value it had assigned to the '815 patent, and applied that value to Abbott's topline number. (*See id.*) WARF then made various deductions and allocation splits before remitting payment to Washington University. (*See id.*) WARF engaged in this process each year in accordance with the Annual Payment Provision in order to calculate Washington University's share of the Abbott royalty stream under the IIA. (*See id.*)
- 231. WARF breached the IIA each year it applied a grossly deficient relative value of the '815 patent to calculate Washington University's annual payments. (*See infra* ¶¶ 291-315) As explained in Paragraphs 293-303 below, WARF's sequential breaches under the IIA are separately actionable under Wisconsin law, despite the fact that WARF's initial breach in the series occurred before the six-year statute of limitations. Under Wisconsin law, each annual breach under an annual payment obligation gives rise to a new statute of limitations period, whether or not there is also an independent, annual duty to revalue. (*See id.*)

- under Wisconsin law, such a duty existed here. (*See infra* ¶ 304-315.) As WARF's tech transfer expert, Dr. Severson, acknowledged, WARF had a duty to revisit its value allocations under the IIA in the face of an appropriate challenge by Washington University. (Trial Tr. 1028:22-1029:4 (Dr. Severson); *see also* Trial Tr. 327:10-328:15 (Dr. Cleare).) Of course, a condition precedent to WARF's duty to revalue in that situation is that Washington University actually raise a challenge. But in this case, WARF's misconduct prevented Washington University from learning information that Washington University needed to determine if it had a valid claim. (*See* Proposed FOF ¶ 66-95, 119-140.) Washington University's failure to raise a challenge to each annual underpayment under the IIA is therefore excused under settled law that the implied covenant of good faith and fair dealing prohibits a party from preventing the occurrence of a condition of that party's duty. (*See supra* ¶ 201-202; *see infra* ¶ 308-315.)
- 233. WARF has argued that the implied covenant of good faith and fair dealing did not require WARF to revisit its initial relative value assignment when calculating Washington University's annual payments, even if WARF *knew* its annual payments were insufficient to fairly compensate Washington University for licensing revenue generated by the parties' co-owned patent. At trial, WARF's tech transfer expert, Dr. Severson, disagreed with WARF's position. Dr. Severson admitted that WARF, as the senior party, had a duty to revalue if it knew its original valuation was mistaken because WARF had a duty to be fair to Washington University under the IIA. (Trial Tr. 1028:4-21 (Dr. Severson).) WARF therefore breached the IIA by failing to correct its relative value allocation to the '815 patent each year it used its mistaken allocation to calculate Washington University's annual payments.
 - 234. Because WARF wrongfully prevented Washington University from raising a

challenge a condition precedent to WARF's duty to correct the value it applied to Washington University's annual payments, WARF breached the IIA each year it made annual payments under a grossly deficient relative valuation of the '815 patent. *See Designer Direct*, 313 F.3d at 1046-47 (defendant's actions "violated the standards of fairness and reasonableness" when they "undermine[d] the communication, [and] the cooperation essential to successful completion of the contract"); *Market Street Assocs.*, 941 F.2d at 592, 597 (if party's breach of implied covenant prevents negotiations from taking place that are a condition precedent to its duty, those negotiations are excused, and a duty is imposed by law).

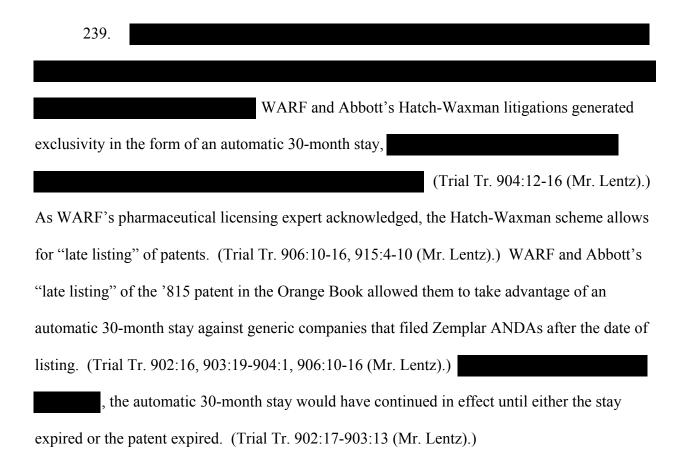
2. WARF Owes Washington University Damages

- 235. Washington University seeks damages from WARF based on the amounts WARF should have paid to Washington University under a fair relative value of the '815 patent. As discussed below, Washington University's damages expert has ascertained that a fair relative value of the '815 patent is between 29% to 33% of the relative value of the Abbott portfolio in the 1998 Abbott License. Washington University presents its specific damages calculations below when discussing Wisconsin's equitable estoppel and periodic payment rules.
- 236. "The fundamental idea in allowing damages for breach of contract is to put the plaintiff in as good a position financially as he would have been in but for the breach. Damages are the compensation which the law will award for an injury done." *Schubert v. Midwest Broad.*Co., 85 N.W.2d 449, 452 (Wis. 1957). The measure of damages for a breach of contract is therefore the amount that will compensate the party for the loss suffered because of the breach.
 Thorp Sales Corp. v. Gyuro Grading Co., 331 N.W.2d 342, 346 (Wis. 1983). The injured party is entitled to the benefit of his agreement, which is the net gain he or she would have realized from the contract but-for the failure of the other party to perform. *Id.* Similarly, in breach of good faith and fair dealing cases, plaintiffs may recover "for all detriment proximately resulting"

from the breach. *Danner v. Auto-Owners Ins.*, 629 N.W.2d 159, 177 (Wis. 2001).

- 237. As a result of WARF's self-dealing and arbitrary valuation, WARF grossly undervalued the '815 patent when it assigned it less than a 1% relative value, paid millions and millions of dollars in royalties to dozens of inventors at the University of Madison-Wisconsin who made absolutely no contribution whatsoever to Zemplar, while Dr. Slatopolsky whose seminal study led directly to the issuance of one of the most important patents licensed to Abbott received only a fraction of the royalties as those other inventors. (*See* Proposed FOF ¶¶ 96-114.)
- 238. Washington University suffered damages as a result of WARF's misconduct and underpayment of royalties in breach of the IIA because the '815 patent was one of the most important patents in the 1998 Abbott License, and worth far more than the negligible 0.968% value that WARF allocated to it. (*See* Trial Tr. 527:22-548:6 (Mr. Thomas); *see also* Proposed FOF ¶¶ 96-114.) The '815 patent covered Zemplar's approved indication. (Trial Tr. 528:8-529:6 (Mr. Thomas); JX42 at 1; JX47 at 1; JX50 at 1; JX85, FOF ¶ 71.) Generic forms of Zemplar infringed the '815 patent. (Trial Tr. 528:8-529:6 (Mr. Thomas); JX85, FOF ¶¶ 189-236.) Abbott and WARF asserted the '815 patent in litigation to protect Zemplar's exclusivity. (Trial Tr. 531:9-532:13 (Mr. Thomas); JX58-60; JX63-66; JX416.) The '815 patent's listing in the Orange Book gave rise to automatic 30-month stays in ANDA litigations involving the '815 patent. (Trial Tr. 903:19-904:1 (Mr. Lentz); Trial Tr. 531:24-532:13 (Mr. Thomas); JX415.)

And the '815 patent is the longest-lived patent in the 1998 Abbott License to confer exclusivity over Zemplar. (Trial Tr. 545:9-546:15 (Mr. Thomas).)



240. The '815 patent's relative value goes beyond its exclusionary power. As an exclusively-licensed patent under the 1998 Abbott License that would have been infringed by Zemplar but for the 1998 Abbott License, the '815 patent generated 7% earned royalties on Abbott's sales of Zemplar under the "earned royalty" provision of the 1998 Abbott License. (JX8 at 3; *see also* Trial Tr. 529:7-531:8, 541:23-545:8 (Mr. Thomas); JX426 at 100:5-7, 105:7-17, 109:6-14 (Mr. Stoveken Rule 30(b)(6) testimony); JX85, FOF ¶ 1.) The FDA recognized the importance of Dr. Slatopolsky's '815 patent study during its medical review of Zemplar. (JX52 at 6-7.) The '815 patent study also helped demonstrate Zemplar's superiority over Calcijex in treating patients with chronic kidney disease because the '815 patent taught how to administer Zemplar to treat chronic kidney disease while avoiding hyperphosphatemia. (JX81 ¶ 36; JX82 ¶¶ 15, 56-57; JX83 ¶¶ 63-64, 121; JX85, FOF ¶¶ 254, 328-34; JX87 at 1.) As WARF and

Abbott's expert in the *Hospira* litigation, Dr. Vigil, recognized, the benefits and advantages associated with the '815 patented treatment method substantially contributed to Zemplar's commercial success and 30% price premium over Calcijex, precisely because of the '815 patent's disclosure (and claims) of a method of using paricalcitol while avoiding hyperphosphatemia. (Trial Tr. 532:14-541:17 (Mr. Thomas); JX84 ¶¶ 22, 28, 31-36, 40, 50; JX87 at 1; JX85, FOF ¶¶ 329-334.)

241. As explained in the subsections that below, a fair relative value of the '815 patent falls within a range of at least 29% to 33%. (Trial Tr. 526:18-527:9 (Mr. Thomas).)

a. 33% Relative Valuation

- 242. As shown above, WARF breached the IIA by failing to assign a fair relative value to the '815 patent in light of all the circumstances. If WARF had assigned a fair relative value to the '815 patent, it would have assigned it at least equal value to the '497 and '925 patents because the '815 patent had certain attributes that made it as valuable, if not more valuable, as the '497 and '925 patents. (Trial Tr. 558:4-20 (Mr. Thomas).)
- 243. Significantly, only three patents in the Abbott portfolio the '497, '925, and '815 patents generated "earned royalties" for WARF. (Proposed FOF ¶ 83-85, 102-103.)

 WARF licensed all three on exclusive terms to Abbott pursuant to the 1998 Abbott License, according to WARF's sworn testimony in the *Hospira* litigation. (Trial Tr. 513:16-515:9 (Mr. Stoveken Rule 30(b)(6) testimony).) That means that all three patents equally supported Abbott's obligation to pay "earned royalties" up to the full 7% royalty cap in the 1998 Abbott License, with the '815 patent generating those royalties over a longer duration than either the '497 and '925 patents. (*See id.* ¶ 106.) A fair relative value for the '815 patent would recognize its comparable contribution to the \$427.6 in earned royalties that Abbott paid to WARF for licensing the patents in the Abbott portfolio. (*See id.* ¶ 83-85, 102-103.)

- 244. In addition, of all the patents in the portfolio, only the '497 and '925 patents shared similar value characteristics as the '815 patent. (*See* Proposed FOF ¶¶ 98-114; Trial Tr. 558:4-20 (Mr. Thomas).) Specifically, the '815 patent:
 - Contributed to FDA approval of Zemplar. (Proposed FOF ¶ 67-69, 73-74.)
 - Convinced physicians of Zemplar's superiority over Calcijex. (*Id.* ¶¶ 87-95.)
 - Allowed Abbott to sustain a 30% price increase over Calcijex. (*Id.* ¶ 92.)
 - Covered the only FDA approved indication of Zemplar. (*Id.* ¶¶ 70-72, 75-77.)
 - Was exclusively licensed to Abbott. (*Id.* ¶ 83-85.)
 - Generated 7% earned royalties under the 1998 Abbott License. (*Id.* ¶ 84.)
 - Was infringed by generic forms of Zemplar. (*Id.* ¶ 75-77, 143-147.)
 - Was listable in the Orange Book for Zemplar. (*Id.* ¶ 148-155.)
 - Was assertable in litigation to block generic competition. (*Id.* ¶ 156-158.)
 - Was recognized by generic companies as valid and infringed. (*Id.* ¶ 152.)
 - (*Id.*)
 - (*Id.* ¶ 238)
- 245. Moreover, the '815 patent had elements of value even greater than the '497 and '925 patents. (Proposed FOF ¶¶ 103-106.) The '815 patent expired about 1.55 years after the '497 patent and about 3.24 years after the '925 patent. (*See id.* ¶ 106.) In addition, the '815 patent's teaching of a method of administering paricalcitol while avoiding hyperphosphatemia substantially contributed to Zemplar's commercial success in ways that the '497 and '925 patents did not. (*See id.* ¶¶ 87-95, 103-105.) Both patents disclosed and claimed "many" compounds, including Vitamin D2 and D3 compounds that behave differently on human physiology. (*See id.* ¶ 12, 103.) Until Dr. Slatopolsky's '815 patent study, no one knew which of the many 19-nor

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Vitamin D analogs that Dr. DeLuca had synthesized would be safe and effective for the treatment of patients with chronic kidney disease. (*See id.* ¶¶ 12-20.) The '815 patent's teaching about minimizing blood phosphorous levels enabled Abbott to rapidly convert sales from Calcijex, and sustain revenue streams that would not have been possible without Dr. Slatopolsky's study. (*See id.* ¶¶ 87-95.)

- 246. Because the '815, '497, and '925 patents were the only patents that directly read on the Zemplar compound or the approved use of Zemplar, generated 7% "earned royalties" under the 1998 Abbott License, were listed in the Orange Book, and were asserted in litigation as blocking patents against generic Zemplar those three patents should have received an equal allocation of 33.3% each under a fair valuation. (Trial Tr. 558:4-20 (Mr. Thomas).)
- 247. Finally, despite the '815 patent's greater indicia of value, including its longer patent life and its outstanding contributions to FDA approval and Zemplar's commercial success, assigning equal value to the '497, '925, and '815 patents would fairly compensate Washington University and Dr. Slatopolsky for their contributions to the medical breakthrough drug Zemplar, without diminishing Dr. DeLuca's contributions as the inventor of the paricalcitol compound. Under a 33% relative valuation, WARF would not only retain 67% of the total "earned royalties" from Abbott based on WARF's '425 and '925 patents, but would also retain 67% of the 33% fair value allocation to the '815 patent under the parties' "two-thirds one-third" sharing allocation under the IIA (which also recognized Dr. DeLuca's contributions as the compound patent owner). (See Proposed FOF ¶ 64.)

b. 30% Relative Valuation

248. As shown above, WARF also violated the IIA by engaging in self-dealing, including by improperly allocating 29% relative value to 29 Ancillary Patents that had no demonstrated value as to Zemplar. (*See supra* ¶¶ 218-225.) Correcting for that misallocation

would allocate to the '815 patent, the only ancillary patent of value, all 30% of the relative value assigned to the Ancillary Patents. (Trial Tr. 555:6-556:5 (Mr. Thomas).)

- Abbott portfolio contributed substantial value to Zemplar. (Proposed FOF ¶¶ 107-113.) Six patents disclosed methods of using paricalcitol for which Zemplar had never been approved. (See id. ¶¶ 109-110.) Eighteen Ancillary Patents had nothing to do with making 19-nor Vitamin D2 compounds like Zemplar. (See id. ¶¶ 107-108.) Another Ancillary Patent was entirely duplicative of the '497 patent and served no purpose other than to dilute the '815 patent's royalty share. (See id. ¶¶ 111.) Only four Ancillary Patents potentially related to methods of making Zemplar, but no evidence suggests that Abbott's authorized manufacturing process relied on any of those methods to make Zemplar. (See id. ¶ 112.) None of WARF's fact or expert witnesses disputed Washington University's showing that no Ancillary Patent, other than the '815 patent, contributed substantial value to Zemplar. (See id. ¶ 113.) WARF's own tech transfer expert, Dr. Severson, for example, admitted that he couldn't "identify any Ancillary Patents at all in the 1998 Abbott License that added substantial value to Zemplar." (Trial Tr. 1033:5-8 (Dr. Severson).)
- 250. Mr. Lentz's testimony that assigning no value to the Ancillary Patents would be "a bit harsh" because Abbott "may be using them, may not be" (Trial Tr. 827:4-18 (Mr. Lentz) ignores Dr. Cleare's unrebutted testimony that 25 Ancillary Patents had *no* potential to contribute to Zemplar. (*See* Proposed FOF ¶¶ 107-111.) Only 4 Ancillary Patents *potentially* related to methods of making paricalcitol, but those patents would have been easy to design around, as Dr. DeLuca acknowledged. (*See id.* ¶ 112.) WARF offered no evidence that those 4 Ancillary Patents contributed in any way to Zemplar or generated "earned royalties" under the 1998 Abbott

License. (*See id.*) To the extent Mr. Lentz was suggesting that Abbott might one day obtain a new FDA-approved indication for Zemplar, WARF had a policy and practice of reallocating substantial value to ancillary treatment patents shown to cover an newly anticipated FDA-approved indication, as it did when it assigned 29% relative value to its multiple sclerosis ancillary patent in anticipation of multiple sclerosis revenue. (JX10 at 3; JX15 at 2, 15.)

c. 29% Relative Valuation

- 251. As shown above, WARF also engaged in self-dealing in violation of the IIA by applying an unfair double standard to the '815 patent, allocating it equal value to all other Ancillary Patents on the false pretense that WARF's "policy" required such treatment, while applying a much more preferential standard to ancillary patents solely owned by WARF. (*See supra* ¶¶ 218-225.) Correcting for this unfair double standard would result in an allocation of at least 29% value to the '815 patent. (Trial Tr. 556:6-558:3 (Mr. Thomas).)
- 252. WARF's relative value allocation under the Multiple Sclerosis IDM serves as an informative and useful benchmark of the minimum fair relative value of the '815 patent. In the Multiple Sclerosis IDM, WARF allocated 42% relative value to the '497 compound patent, singled out the Multiple Sclerosis Treatment Patent from all the other Ancillary Patents to receive 29% of any royalties deriving from the Multiple Sclerosis field, and assigned the remaining 29% to all other Ancillary Patents. (JX15 at 2, 14-15.) In other words, WARF did not allocate equal value to all ancillary patents regardless of whether those patents were being used, but assigned substantial value to one ancillary patent that covered an anticipated new indication.
- 253. Because none of the other patents in the Abbott portfolio generated substantial value for Zemplar, a fair relative value allocation under the standards that WARF applied to its own ancillary patents would be a 42% relative value allocation to the '497 patent, with an equal share of the remaining 58% to the two other Orange Book listed patents the '815 and '925

patents — resulting in a 29% relative value allocation to the '815 patent. (Trial Tr. 556:6-558:3 (Mr. Thomas).)

d. 27.1% Relative Valuation

- 254. Mr. Thomas discussed a relative valuation approach of assigning 4% relative value to the 4 Ancillary Patents relating to manufacturing processes that *potentially* related to Zemplar, but where no evidence suggested that Abbott used them or that they generated "earned royalties" under the 1998 Abbott License. (Trial Tr. 559:3-560:7 (Mr. Thomas).) No WARF witness explained why these 4 Ancillary Patents should receive any relative valuation allocation at all. (*See* Proposed FOF ¶ 112.) Without any evidence showing that these 4 Ancillary Patents have value, allocating them any relative value would be unsupported and/or against the great weigh of the evidence. In addition, assigning each of these 4 Ancillary Patents a 0.968% relative value likely overstates the value of those patents. These patents cover processes, syntheses, and intermediates, which are not eligible to be listed in the Orange Book. (*See id.*) In addition, as Dr. DeLuca acknowledged, they would be relatively easy to design around. (*See id.*)
- 255. Assuming 3.9% relative value were allocated to these patents, the '497 patent would receive 42% value and the remaining 54.1% value would be split equally between the '925 patent (27.1%) and the '815 patent (27.1%). (Trial Tr. 559:3-560:7 (Mr. Thomas).)

e. 14.5% Relative Valuation

256. Mr. Thomas also discussed a relative valuation approach of assigning 29% relative value to the 29 Ancillary Patents, with 42% relative value allocated to the '497 patent and 29% value split equally between the '925 (14.5%) and '815 (14.5%) patents. This model has no factual support in the record and is certainly against the great weigh of the evidence.

Allocating 29% to 29 Ancillary Patents that WARF does not contest were valueless with respect to Zemplar would unfairly assign more value to those patents than to the '815 patent. This

model would also reward WARF's self-dealing relative value allocation by allowing WARF arbitrarily to allocate substantial value to patents that played no role in supporting Zemplar at the expense of the parties' co-owned '815 patent.

f. A Proper Relative Valuation Is Between 29% and 33%

- 257. The fair relative value of the '815 patent is therefore between 29% and 33% of the value of the Abbott portfolio, instead of the 0.968% value WARF assigned. A relative value allocation to the '815 patent of between 29% and 33% translates to an effective royalty rate of between about 2.03% to 2.33% as a percentage of Zemplar's sales. (Trial Tr. 1120:12-23 (Ms. Mulhern).) These rates are well supported in light of evidence of the bargained-for rate that Abbott paid for an exclusive license to the '815 patent, which equaled either (1) 7%, assuming the truth of WARF's Rule 30(b)(6) deposition that WARF licensed the '815 patent exclusively to Abbott under the terms of the 1998 Abbott License (Trial Tr. 489:4-9, 514:12-18 (Mr. Stoveken)); or (2) 5.6%, applying WARF's damages expert's calculation of the bargained-for rate on a blended basis, assuming that WARF's license to the '815 patent became exclusive for the first time in 2012. (Trial Tr. 1124:5-10 (Ms. Mulhern).)
- 258. A damages award at the higher end of this range would be appropriate in view of evidence that the '815 patent had a longer patent life than the '497 and '925 patents, substantially contributed to Zemplar's commercial success in ways that the '497 and '925 patents did not, and had substantially more value than any of the other Ancillary Patents.

3. Washington University Also Seeks Prejudgment Interest

259. Washington University also seeks any further and additional relief as this Court may deem just and proper, including prejudgment and postjudgment interest. Wisconsin law recognizes the availability of prejudgment interest in breach of contract cases to fully

compensate the injured party.⁹ "The general rule is that prejudgment interest may be recovered only when damages are either liquidated or liquidable, that is, there is a reasonably certain standard of measurement by the correct application of which one can ascertain the amount he or she owes." *Teff v. Unity Health Plans Ins. Corp.*, 666 N.W.2d 38, 53 (Wis. Ct. App. 2003). The rationale for this rule is that "if the amount of damages is either liquidated or determinable by reference to some objective standard, the defendant can avoid the accrual of interest by simply tendering to the plaintiff a sum equal to the amount of damages." *Id.* Here, Washington University's damages are determinable by "reference to some objective standard" — namely, WARF's own relative valuation methods as applied to patents similarly situated to the '815 patent. Had WARF applied its own written policy when assigning value to the '815 patent, it would have taken into consideration the objective value attributes of the '815 patent, comparing them to the same objective attributes of the other patents in the Abbott portfolio. Such an analysis would have yielded a reasonable range of fair relative values between 29% and 33%.

260. WARF has argued that prejudgment interest cannot be ascertained with reasonable certainty where a contract is ambiguous and genuine disputes exist over how to interpret a contractual provision relating to the determination of damages. But here, as in *Teff*, any "dispute over the proper method under the contract for determining the amount of reconciliation payments did not require the resolution of factual issues." *Teff*, 666 N.W.2d at 53-54. WARF's only purported "factual disputes" over the objective value attributes of the '815 patent involved repudiating facts that WARF unequivocally championed in the *Hospira* litigation. In the *Hospira* litigation, WARF elaborated at length on the value attributes that made the '815 patent one of the most important patents in the portfolio, including that it covered

⁹ In Wisconsin, prejudgment interest accrues at a rate of five percent. Wis. Stat. § 138.04 (2017).

Zemplar's approved use and therefore was infringed by generic Zemplar (*see* Proposed FOF ¶ 184-188); that it was licensed exclusively to Abbott and generated 7% earned royalties under the 1998 Abbott License (*see id.* ¶ 176-183); and that it substantially contributed to Zemplar's commercial success (*see id.* ¶ 189-195). WARF's repudiation of its positions in the *Hospira* litigation did not create any "genuine disputes," particularly where no WARF witnesses could adequately explain the glaring inconsistency between WARF's positions in the *Hospira* litigation and WARF's positions in this lawsuit. (*See id.* ¶ 176-195.) WARF should not be allowed to capitalize on its repudiation of the statements it made about the '815 patent's objective value attributes in the *Hospira* litigation merely to deny Washington University full compensation for the harm that WARF's multiple breaches of the IIA caused. *See Giffen v. Tigerton Lumber Co.*, 132 N.W.2d 572, 575 (Wis. 1965) ("Mere difference of opinion as to amount [owed] is, however, no more a reason to excuse him from interest than [a] difference of opinion whether he legally ought to pay at all, which has never been held an excuse.").

dispute as to which of the extra charges were necessary and properly authorized." *Loehrke v. Wanta Builders, Inc.*, 445 N.W.2d 717, 722 (Wis. Ct. App. 1989). Here, WARF does not dispute Washington University's method of calculating damages, and WARF's repudiation of its prior admissions about the '815 patent's value do not give rise to a genuine dispute over damages. Similarly, in *Jones v. Jenkins*, 277 N.W.2d 815, 820 (Wis. 1979), the court denied prejudgment interest because damages under the contract "did not have to be paid until the assets had been distributed, an event which had not occurred as of the time of trial" in that case. Here, by contrast, WARF breached the IIA each year it underpaid Washington University royalties due under a fair relative valuation of the '815 patent— *i.e.*, events that occurred in the past.

262. Washington University discusses its specific damages and interest calculations below in light of the effect of Washington University's equitable estoppel and periodic payment claims against WARF's inability to assert the statute of limitations on the facts of this case. Washington University's interest calculations (as well as an alternative damages calculation inquired into by the Court at trial) are further supported by the Declaration of Vince Thomas in Support of Washington University's Proposed Findings of Fact and Conclusions of Law.¹⁰

B. WARF's Statute of Limitations Defenses Do Not Apply

263. Washington University's claims are not barred by the statute of limitations. First, WARF's fraudulent and inequitable misconduct equitably estops WARF from asserting a statute of limitations defense against Washington University's contract claims. Alternatively, Wisconsin's periodic payment rule allows Washington University to assert breach of contract claims based on each of WARF's annual payments based on an improper relative value of the '815 patent within the six-year period before the Standstill Agreement on April 9, 2013.

1. Equitable Estoppel Bars WARF from Asserting a Statute of Limitations Defense

- 264. The clear and convincing evidence at trial established that the doctrine of equitable estoppel bars WARF from asserting the statute of limitations in this case.
- 265. "The doctrine of equitable estoppel applies where there is: '(1) action or non-action; (2) on the part of one against whom estoppel is asserted; (3) which induces reasonable reliance thereon by the other, either in action or non-action; (4) which is to the relying party's detriment." Wash. Univ., 703 F. App'x at 109 (citing Affordable Erecting, Inc. v. Neosho Trompler, Inc., 715 N.W.2d 620, 628 (Wis. 2006)).

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¹⁰ Mr. Thomas calculated prejudgment interest using the Wisconsin statutory rate of five percent simple interest. *See* Wis. Stat. § 138.04 (2017).

- party to file a claim." *Wash. Univ.*, 703 F. App'x at 109 (citing *Barry Aviation, Inc. v. Land O'Lakes Mun. Airport Comm'n*, 377 F.3d 682, 689 (7th Cir. 2004)). "The conduct or representations of the party asserting the statute of limitations must be 'so unfair and misleading as to outbalance the public's interest in setting a limitation on bringing actions." *Id.* (quoting *State ex rel. Susedick v. Knutson*, 191 N.W.2d 23, 26 (Wis. 1971)). Equitable estoppel requires proof by clear and convincing evidence. *Gonzalez v. Teskey*, 465 N.W.2d 525, 530 (Wis. Ct. App. 1990).
- 267. Actual fraud is not required to invoke equitable estoppel. Estoppel requires only a showing of fraudulent or inequitable conduct that induced reasonable reliance; it does not require a showing of actual fraudulent intent. *Susedik*, 191 N.W.2d at 26 ("Actual fraud, in a technical sense, is not required to find estoppel *in pais*."); *Pick Foundry, Inc. v. Gen. Door Mfg. Co.*, 55 N.W.2d 407, 411 (Wis. 1952) ("[A]ctual fraudulent intent is not a necessary incident to the application of the principle of estoppel").
- 268. In *Policemen's Annuity & Benefit Fund, City of Milwaukee v. City of Milwaukee*, 630 N.W.2d 236, 243-44 (Wis. Ct. App. 2001), for example, a Wisconsin appeals court agreed that equitable estoppel arose from the City's *inadvertent failure* to pay into a pension fund in violation of its contractual obligations under a bargaining agreement. The plaintiffs in that case "relied on the City to keep its promise, and it had no idea that the City failed to make such payments" until they discovered it after the statute of limitations had elapsed. 630 N.W.2d at 244. There, as here, "the [plaintiffs] acted promptly to protect its rights" after it discovered the breach. *Id.* The Wisconsin appeals court easily found that the City's failure to catch its mistake constituted "wrongful conduct" that "the other side has relied on the conduct to its detriment."

Id. at 243.

- 269. Similarly, in *Barry Aviation*, 377 F.3d at 690, defendants engaged in "concealment of evidence" and "diversionary explanations" that, among other things, "combined to keep the plaintiff from suing when it was first injured." The Seventh Circuit therefore reversed the district court's denial of leave to amend the plaintiff's complaint, finding that complaint set forth facts demonstrating that defendants "concealed evidence from the plaintiff that [it] needed to determine that [it] had a claim." *Id.* at 689. Likewise, in *Comcast of Ill. X, Ltd. Liab. Co. v. Multi-Vision Elecs., Inc.*, No. 8:03CV311, 2005 U.S. Dist. LEXIS 32702, at *20-21 (D. Neb. Sep. 8, 2005), the court concluded that equitable estoppel barred the defendant's assertion of a statute of limitations defense because defendant "at least obscured, if not concealed" the facts needed for the plaintiff to detect a breach and the plaintiff leaned the truth only "as a result of discovery."
- element of its equitable estoppel claim. As the Third Circuit determined in this case, the parties disputed the following factual issues at the summary judgment phase: "(1) whether WARF concealed information Washington University needed to determine if it had a valid claim, (2) whether that information was necessary to pursue the claim, (3) whether Washington University reasonably relied on WARF's statements and conduct, and (4) whether Washington University had the ability to obtain that information, notwithstanding WARF's alleged concealment." *Wash. Univ.*, 703 F. App'x at 110. The Third Circuit stated that its identification of specific factual disputes in its opinion was "not intended as an exhaustive listing of the issues of material fact" and that it identified those issues "merely to illustrate that this record does not support summary judgment, and WARF was therefore not entitled to judgment as a matter of

law." (D.I. 141-2 at 8 n.22.) Washington University addresses each of these elements below.

- a. WARF Concealed Information That Washington University Needed to Determine If It Had a Valid Claim
- 271. WARF engaged in multiple modes of concealment, misrepresentation, and misdirection in the six-year period after WARF's breach in October 1998, which concealed material information Washington University needed to determine if it had a valid claim.
- 272. **First**, even though Washington University reasonably expected that WARF would keep Washington University's tech transfer office in the loop about key information bearing on the value of the parties' co-owned '815 patent, WARF kept all material information about the value of the '815 patent to itself. (Proposed FOF ¶¶ 66-95.) As of WARF's April 4, 2001 letter explaining why WARF had assigned less than 1% relative value to the '815 patent, Washington University's tech transfer office did not know what WARF knew: that the '815 patent study helped convince the FDA and prescribing physicians of Zemplar's advantages over Calcijex (see id. ¶¶ 67-69, 73-74); that the '815 patent claims provided "additional protection" for and "directly support[ed]" Zemplar (see id. ¶¶ 70-72, 75-77); even though Zemplar was approved for SHPT, physicians would prescribe Zemplar to treat RO anyway, as recited in the '815 patent claims, based on the equivalence of SHPT and RO (see id. ¶ 75); and that the '815 patent was one of only three patents to generate "earned royalties" under the 1998 Abbott License (see id. ¶ 78-86). Without this information, which WARF actively concealed from Washington University in violation of its promises under the IIA and applicable professional standards (see id. ¶¶ 27-39), Washington University lacked needed context to evaluate WARF's assertions in its April 4, 2001 letter that the '815 patent was "ancillary" and of negligible "0.968%" value. (See id. ¶¶ 119-140.)
 - 273. **Second**, in WARF's May 13, 1998 email to Washington University (JX46),

WARF refused Washington University request to see "any [Abbott] license and/or amendment that has either been executed or has the potential of being executed in the near future" by falsely representing that "confidentiality provisions" prevented their disclosure to Washington University. (Proposed FOF ¶¶ 79-80.) WARF's own tech transfer expert, Dr. Severson, admitted that no such "confidentiality provisions" existed. (Trial Tr. 989:1-5 (Dr. Severson).) Dr. Severson also admitted that Washington University needed access to the 1998 Abbott License to determine whether it had a valid claim because "without knowing the identities of the patents included in the 1998 Abbott License, Washington University couldn't determine or evaluate whether WARF had assigned a fair relative value to the 815 patent in proportion to the other patents in the portfolio." (Trial Tr. 989:12-22 (Dr. Severson).) Washington University learned only through civil discovery in this lawsuit that WARF had allocated equal value to the '815 patent and dozens of patents in the Ancillary Patents group that had no value with respect to Zemplar, as WARF's experts conceded. (Proposed FOF ¶¶ 107-113.)

Third, in WARF's April 4, 2001 letter to Washington University (JX49), WARF falsely represented that "[t]he License Agreement from which royalties are generated has a portfolio of patents relating to the Vitamin D compound that is licensed." (Proposed FOF ¶ 127-128.) As Washington University's tech transfer expert Dr. Cleare testified, and as no WARF fact or expert witness rebutted, WARF had included at least 18 Ancillary Patents in the 1998 Abbott License that did not relate to the licensed paricalcitol compound, contrary to WARF's representation in its April 4, 2001 letter that "portfolio of patents" licensed to Abbott related to the "compound that is licensed." (See id. ¶¶ 107-108.) As Dr. Cleare showed, none of those 18 Ancillary Patents related to methods of making 19-nor Vitamin D analogs like paricalcitol, and nearly all of them dated back to the early 1980s, about a decade before Dr.

DeLuca first synthesized paricalcitol. (*See id.*) Yet, each of those patents received equal value as the '815 patent. (*See id.*) WARF's false assertion that all patents in the 1998 Abbott License related to the licensed paricalcitol compound misleadingly suggested that all Ancillary Patents had equal "ancillary" value next to the compound patent for paricalcitol, when in fact the majority of them had nothing to do with paricalcitol at all. (*See id.*)

- WARF falsely represented that it had assigned 70% relative value to the "compound patents" plural "in accordance with WARF's regular practice" with respect to the Vitamin D portfolio. (See Proposed FOF ¶ 129-133.) WARF's own tech transfer expert, Dr. Severson, admitted that this representation was false: "[t]here was only one compound patent in the 70 percent group of the 1998 Abbott License," i.e., the '497 Patent. (Trial Tr. 991:7-23 (Dr. Severson) (emphasis added).) "The other patent in that group," Dr. Severson acknowledged, "was the '925 patent, which was a method of treatment patent." (See Trial Tr. 991:7-23 (Dr. Severson).) Dr. Severson agreed that the '925 patent received a full 35% relative value allocation by virtue of its inclusion in the 70% group. (Trial Tr. 992:19-993:2 (Dr. Severson).) This highly material fact strongly undermined WARF's assertion in its April 4, 2001 letter that only "compound patents" received substantial value under the WARF's valuation practices, and that everything else including treatment patents like the '815 patent were "ancillary" and of negligible value.
- 276. Although Dr. Severson attempted to explain away this misrepresentation by claiming that WARF's reference to "compound patents" was an "internal moniker" for the '497 and '925 patents, WARF had no trouble explaining internally in its October 16, 1998 valuation memorandum that "the compound *and the primary indication[]* will receive a relative value of 70%." (Proposed FOF ¶ 131.) WARF cannot claim the author of the April 4, 2001 letter —

Jodie Armstrong (who copied WARF's General Counsel on the letter) — did not know this highly material fact since she (and WARF's General Counsel) also received WARF's internal October 16, 1998 valuation memorandum. (*See id.*) WARF has offered no explanation why it concealed this same information to Washington University. In any event, it is undisputed that WARF never told Washington University about its alleged use of the term "compound patents" as an "internal moniker" to refer to a compound patent and a method of treatment that covered Zemplar's approved indication. (Trial Tr. 991:15-992:5, 993:15-23 (Dr. Severson).)

Fifth, in WARF's April 4, 2001 letter to Washington University (JX49), WARF falsely represented that "[i]t is WARF's policy to allocate evenly among these patents regardless of whether or not the patent is actually currently being used by the Licensee." (Proposed FOF ¶¶ 134-135.) WARF's own tech transfer expert, Dr. Severson, admitted that he had never seen any "WARF policy" embodying that statement. (Trial Tr. 994:8-17 (Dr. Severson).) To the contrary, as Dr. Severson acknowledged, "WARF's written policy says that WARF has discretion to assign unequal values based on a patent's contribution to the development and commercialization of the drug," and that it "makes no distinction between capitalized Licensed Patents and capitalized Ancillary Patents." (Trial Tr. 998:4-13 (Dr. Severson).) WARF never communicated this written policy to Washington University. (Trial Tr. 998:4-17 (Dr. Severson).) WARF's assertion that it had a "policy" of assigning equal value to all Ancillary Patents regardless of use, when its actual policy said the opposite, communicated to Washington University that WARF had applied a fair and evenhanded approach that distinguished between "compound patents" and everything else. (Proposed FOF ¶¶ 134-135.) Without knowing that WARF's policy allowed substantial value allocations to any patent in the portfolio, ancillary or not, Washington University did not know that WARF had discretion to deviate from its

"blended" approach where, as here, an ancillary patent "directly support[ed]" the licensed drug. (See id.)

- claiming that WARF had a "regular practice" (as opposed to a "policy") of assigning equal value to all ancillary patents regardless of use, Dr. Severson admitted that WARF did not allocate value equally to all ancillary patents when it came to its own multiple sclerosis ancillary patent that contributed to the development and commercialization of an anticipated Multiple Sclerosis indication. (Proposed FOF ¶ 134.) Dr. Severson testified that he was unable to reconcile WARF's application of a more favorable standard to its own Multiple Sclerosis ancillary patent, with WARF's "equal allocation" approach to the parties' co-owned ancillary patent, even though WARF knew both treatment patents read on the relevant indication or anticipated indication. (See id.) Such practices, he acknowledged, violated WARF's obligations to be fair to Washington University under the IIA. (See id. ¶ 135.) Without honest and accurate information about WARF's actual policies and practices with respect to ancillary patents that directly supported the licensed drug, Washington University did not know that its "ancillary patent" could receive a substantial (e.g., 29%) value allocation. (See id.)
- 279. **Finally**, in WARF's April 4, 2001 letter to Washington University (JX49), WARF misleadingly suggested that "it was difficult if not impossible for WARF to determine whether or not the patent is being used by the Licensee at this time." (Proposed FOF ¶¶ 136-137.) But at the time of WARF's April 4, 2001 letter, WARF had already performed an extensive evaluation of the Abbott portfolio patents and concluded that the '815 patent "directly support[ed]" Zemplar. (*See id.* ¶¶ 75-77.) In addition, by that time, a number of patents or patent applications in the Abbott portfolio had expired or been abandoned, including a transplant

rejection patent application that WARF had abandoned in January 1999. (*See id.* ¶ 109.)

WARF's own tech transfer expert, Dr. Severson, testified that he had "no information" to explain how it was "difficult if not impossible" for WARF to determine if Abbott was using WARF's abandoned transplant rejection patent application at the time of the April 4, 2001 letter. (Trial Tr. 1002:19-1003:16 (Dr. Severson).) Without access to WARF's internal files, therefore, Washington University did not have access to relevant information needed for Washington University to detect WARF's breach.

- b. The Information WARF Concealed and Misrepresented Was Necessary for Washington University to Pursue Its Claim
- 280. The information that WARF concealed from Washington University was necessary for Washington University to pursue its claim. As WARF's own tech transfer expert, Dr. Severson, acknowledged, Washington University could not evaluate WARF's assertions about the relative value it had assigned to the '815 patent without knowing the identities of the other patents in the 1998 Abbott License. (Proposed FOF ¶¶ 81-82.) Similarly, Washington University could not evaluate WARF's self-dealing overvaluation of the solely-owned WARF patents in the 1998 Abbott License, or the double standard that WARF had applied when assigning value to its own patented treatment methods as compared to the co-owned '815 patented treatment method. (See id. ¶¶ 83-86, 107-113.) Nor could Washington University evaluate WARF's representations about the documents within WARF's exclusive control, such as the nonexistent "confidentiality provision" that WARF represented were present in the relevant Abbott License agreements or the nonexistent "policy" that WARF represented it had of assigning equal value to all ancillary patents regardless of their use by the licensee. (See id. ¶ 80.) Dr. Severson admitted that he did not even see the relevance of the '815 patent to Zemplar until he learned about it from WARF's files after he signed his expert report. (Trial Tr. 1027:4-

18 (Dr. Severson).) Not surprisingly, WARF's fraudulent conduct succeeded in keeping Washington University in the dark about WARF's multiple breaches of the IIA.

c. Washington University Reasonable Relied on WARF's Statements and Conduct

- Washington University reasonably relied on WARF, as the senior party, to uphold 281. its end of the parties' bargain to assign a fair relative value to the '815 patent in light of all the circumstances. (Proposed FOF ¶ 37-39, 138-140.) WARF's expert admitted that Washington University reasonably expected that (1) WARF would deal with Washington University fairly and honestly under the IIA, (2) WARF would use all information known about the '815 patent's value when conducting a relative value analysis, (3) WARF would not apply an unfair double standard when assigning relative value to the parties' co-owned patent, and (4) WARF would provide honest and accurate information about how it valued the parties' co-owned patent. (See id.) The fact that the IIA required WARF to use "all reasonable efforts to cooperate" with Washington University and to administer all license agreements for the "mutual benefit of the parties" further underscores Washington University's reasonable reliance on WARF's valuation activities and explanations under the IIA. (See id.) Washington University's payment of a 15% administration fee to WARF also underscores that Washington University reasonably expected WARF would provide professional, competent, and fair services in exchange for that fee (which totaled nearly \$620,000 over the duration of the parties' relationship). (See id.)
- 282. In addition, because WARF controlled all material information regarding the fair value of the parties' co-owned '815 patent relative to the WARF-owned patents licensed with it, Washington University had no reason to suspect that WARF had ignored material information when it informed Washington University that, in WARF's professional judgment, the '815 patent was "ancillary" to Zemplar and worth 0.968% value compared to WARF's patents. (Proposed

FOF ¶¶ 66-95, 140.) As Washington University's Mr. Kratochvil, testified, Washington University's tech transfer office relied on WARF as the senior party to alert it to important information and events concerning the parties' co-owned '815 patent. (*See id.* ¶ 38.) Washington University's reliance was manifestly reasonable in light of WARF's contractual commitments under the IIA and WARF's professional obligations as the "senior party" to a university IIA. (*See id.* ¶¶ 37-39, 138-140.)

- 283. WARF's tech transfer expert, Dr. Severson, admitted that Washington University had no duty of oversight with respect to WARF's performance under the IIA. (*See id.* ¶¶ 38, 140.) To the contrary, WARF owned a duty to keep Washington University reasonably informed about the parties' shared mission to commercialize the '815 patent and share the resulting royalties. (*See id.*) Dr. Severson also admitted that Washington University had no reason to suspect that WARF not being "straightforward" when it refused Washington University's request to see all past or future Abbott License agreements based on "confidentiality provisions" that turned out not to exist. (Trial Tr. 990:6-10 (Dr. Severson); *see also* Proposed FOF ¶ 80.) These admissions from WARF's expert further demonstrate Washington University's reasonable reliance on WARF's representations about the value of the '815 patent relative to the WARF-owned patents licensed with it. (*See* Proposed FOF ¶ 80.)
- 284. WARF has argued that Washington University failed to keep adequate records and that this somehow justifies WARF's fraudulent and wrongful conduct. But WARF has never argued that it shared information about the '815 patent's value with Washington University, and that Washington University misplaced and forgot about that information. To the contrary, WARF's experts have admitted that they have seen no evidence that WARF shared information about the '815 patent's value with Washington University at all. (Proposed FOF

¶¶ 67-95.) In addition, WARF's argument overlooks that Washington University maintained a copy of WARF's April 4, 2001 letter in its files (*see id.*), which illustrates the materiality of WARF's representations and Washington University's reliance on them. Finally, WARF's own misconduct appears to have contributed to Washington University's record keeping issues.

WARF has admitted that it filed incorrect patent assignment information with the PTO, resulting in WARF's name alone appearing as the "assignee" of the patent. (*See id.* ¶¶ 161-165.) This mistake appears to have caused confusion internally at Washington University about Washington University's ownership interest in the '815 patent, which may help explain why Washington University did not retain copies of routine papers relating to the '815 patent, such as the patent's prosecution history and administrative correspondence with WARF.

285. WARF has also argued that Washington University should have asked WARF multiple times for the information it needed to detect WARF's breach, such as the identities of the WARF-owned patents in the Abbott portfolio. But Washington University ran that experiment in 2012, after Washington University received a subpoena from Hospira that alerted it to WARF and Abbott's assertion of the '815 patent in litigation to block generic Zemplar. (Proposed FOF ¶ 169-174.) Washington University asked WARF multiple times for the identities of the Abbott portfolio patents so that Washington University could evaluate its potential claims against WARF. (*See id.*) WARF stonewalled. WARF perpetuated its misrepresentation that all treatment method patents are "meaningless and largely irrelevant," knowing that WARF had assigned 35% relative value to a WARF-owned treatment method patent (the '925 patent) that, like the '815 patent, covered the approved use of Zemplar. (*See id.* ¶ 171.) Despite asking multiple times for the information Washington University needed to evaluate its claims, as WARF argues Washington University should have done in 1998 or 2001,

the evidence shows that WARF would have continued its campaign of deceit and misdirection. (See id. ¶¶ 169-174.)

- 286. WARF has also misleadingly argued that Washington University purportedly "admitted" that Washington University pursued this lawsuit in 2012 allegedly based on the same information that Washington University had access to in 2001. The critical difference between 2001 and 2012, of course, was that Washington University had access to WARF's assertions in the *Hospira* lawsuit that the '815 patent had been listed in the Orange Book and asserted in litigation to block generic competition for Zemplar. (*See id.* ¶ 148-165.) Washington University also encountered misleading and obstructive statements from WARF in 2012 and 2013 when Washington University asked WARF for information. (*See id.* ¶ 171, 174.) Washington University's lawsuit in 2013 brought civil discovery that finally exposed WARF's misconduct.
 - d. Washington University Did Not Have the Ability to Obtain That Information Notwithstanding WARF's Concealment and Misrepresentation
- 287. Washington University could not obtain any of the information that WARF concealed through any source other than WARF. (Proposed FOF ¶ 67-95.) WARF had exclusive control over Washington University's access to the 1998 Abbott License and therefore the identities of the other patents in the Abbott portfolio (as well as their expiration dates). (*See id.* ¶ 78-86.) WARF's own tech transfer expert, Dr. Severson, admitted that Washington University could not evaluate WARF's relative value assignment to the '815 patent without knowing the identities of the other patents in the 1998 Abbott License. (*See id.* ¶ 82.) WARF also had exclusive control over WARF's policies and practices when assigning relative value to patents licensed as part of a portfolio, including that WARF had assigned between 29% and 35% value to patented treatment methods, like the '815 patent, that directly supported the FDA indication of the licensed drug. Dr. Severson acknowledged that he had seen no evidence that

WARF disclosed those policies or practices to Washington University. (See id. ¶¶ 127-140.)

- 288. WARF also had exclusive control over the information known to WARF about the '815 patent's contributions to development and commercialization of Zemplar, including Abbott's decision not to pursue an RO indication for Zemplar because they knew physicians would prescribe Zemplar to treat both based on the equivalence of SHPT and RO, and WARF's determination that the '815 patent "directly support[ed]" Zemplar even after the FDA's rejection of an RO indication. (Proposed FOF ¶¶ 75-77.) Dr. Severson admitted that even though he had 30 years of experience in the university tech transfer industry, not even *he* realized that the '815 patent had substantial value until he reviewed WARF's internal files showing WARF's knowledge of the equivalence of SHPT and RO dating back to April 1998. (*See id.* ¶ 187.)
- "reverse calculation" to learn the gross royalty income that WARF received from Abbott, and thus could have known what proportion of that royalty income Washington University received. Washington University does not allege that it lacked knowledge of WARF's less than 1% allocation to the '815 patent, but that WARF concealed and misrepresented information Washington University needed to perceive that WARF had undervalued that patent. (*See* Proposed FOF ¶ 66-95, 107-113, 127-137.) Any "reverse calculation" of the total amount of royalties Abbott paid to WARF would not have allowed Washington University to determine whether WARF's annual payments to Washington University fairly reflected the relative worth of the '815 patent, since WARF had actively concealed from Washington University all relevant value information about the 815 patent, the identities of the WARF-owned patents included in the Abbott portfolio, and thus the means to evaluate WARF's assertions that the '815 patent had negligible value.

e. Washington University's Damages Under an Equitable Estoppel Theory

290. Washington University has established all elements of the equitable estoppel doctrine, barring WARF from asserting the statute of limitations, and allowing Washington University to assert claims from the date of WARF's first annual underpayment on November 25, 1998 (JX21), which covered the period from July 1, 1997 to June 30, 1998 (*see* JX1 § 5(B)). Damages dating back to July 1, 1998 are as follows:

RV%	Damages Scenario	Equitable Estoppel (July 1, 1997)	Prejudgment Interest	Total
33%	Treat '497, '925, '815 equally	\$ 39,208,887	\$ 18,444,216	\$ 57,653,103
30%	'815 is only Ancillary Patent with substantial value	\$ 35,170,914	\$ 16,546,238	\$ 51,717,151
29%	Treat '815 same as WARF treated multiple sclerosis ancillary patent	\$ 33,959,522	\$ 15,976,844	\$ 49,936,366
27.1%	Allocate 4% to 4 Ancillary Patents that potentially relate to making paricalcitol	\$ 31,617,498	\$ 14,876,017	\$ 46,493,514

- 2. Alternatively, the Periodic Payment Rule Permits Washington University to Recover Damages Based on WARF's Annual Underpayments of Royalties Within the Limitations Period
- 291. Washington University also meets the requirements of Wisconsin's periodic payment doctrine. First, under long-settled Wisconsin precedent, each of WARF's annual underpayments to Washington University breached the IIA, giving rise to a series of claims on an annual basis, with each claim subject to its own six-year statute of limitations. Alternatively,

to the extent the Court requires finding that WARF had a duty to revalue the '815 patent as a prerequisite for applying Wisconsin's periodic payment doctrine — although Washington University believes this position misreads Wisconsin law and the Third Circuit's opinion in this case — Washington University showed that WARF had a duty to revalue

- 292. These two theories are discussed in detail below.
 - a. Under Wisconsin Law, Washington University May Recover Damages Dating Back to July 1, 2006
- 293. Because the IIA contained an Annual Payment Provision, Washington University may appeal to Wisconsin's periodic payment doctrine to assert claims for breach based on WARF's annual underpayments covering royalty periods dating back to July 1, 2006.
- 294. Contract claims are ordinarily subject to a six-year statute of limitations period in Wisconsin. *See* Wis. Stat. § 893.43 (2017). Under Wisconsin law, however, where a party has an obligation to make "periodic payments" under a contract, as WARF did here, a new claim for breach of contract arises upon each improper periodic payment, triggering a new six-year limitations period from the date of each periodic payment. *See Wash. Univ.*, 703 F. App'x at 108 ("[G]enerally a new claim accrues for each separate breach . . . [, and] the injured party may assert a claim for damages from the date of the first breach within the period of limitation.") (quoting *Noonan v. Nw. Mut. Life Ins. Co.*, 687 N.W.2d 254, 262 (Wis. Ct. App. 2004)).
- 295. As multiple decisions from Wisconsin courts dating back over 135 years make clear, it makes no difference that WARF's improper annual payments trace back to a single event *e.g.*, its October 1998 relative valuation outside the limitations period. In *Butler v. Kirby*, 10 N.W. 373, 374-75 (Wis. 1881), an employee's claims for underpayments within six years before filing suit were timely even though each underpayment traced back to an earlier dispute over whether the monthly salary was \$40 or \$48. In *Jensen v. Janesville Sand & Gravel Co.*,

415 N.W.2d 559, 562 (Wis. Ct. App. 1987), claims beginning six years before suit were timely even though the breaches were based on the company's earlier decision to repudiate the contract. The same was true in *Noonan*, 687 N.W.2d at 262, even though all underpayments traced back to the defendant's decision to change the way it calculated annuity payments, which occurred before the six-year limitations period. And in *Policemen's Annuity*, 630 N.W.2d at 242, the same result obtained even though all payments were calculated based on the same formula beginning thirty years before suit was filed.¹¹

296. Despite this longstanding Wisconsin authority, WARF has argued that if a single event outside the limitations period gave rise to the annual underpayments that form the basis of Washington University's contract claims, that Wisconsin's periodic payment rule does not apply at all, and that *all* Washington University's annual underpayment claims are time barred.

WARF's argument is based solely on *dicta* from two inapposite cases that have been criticized and distinguished in subsequent decisions. In *Messner Manor Associates v. Wisconsin Housing*& Economic Development Authority, 555 N.W.2d 156, 160 (Wis. Ct. App. 1996), the appellate

¹¹ See also Jahn Transfer, Inc. v. Horizon (H&S) Freightways, Inc., 819 N.W.2d 563, 2012 Wisc. App. LEXIS 484, at *4-7 (Wis. Ct. App. 2012) (unpublished but citable for persuasive value under Wis. Stat. § 809.23(3)(b) (2017)) (finding that each alleged underpayment under profit-sharing agreement relating to shipping services gave rise to a distinct actionable breach for purposes of Wisconsin's six-year statute of limitations); Md. Staffing Servs., Inc. v. Manpower, Inc., 936 F. Supp. 1494, 1508 (E.D. Wis. 1996) ("[B]ecause the complaint alleges a series of breaches of the contract, the plaintiffs may assert a claim for damages from the date of the first breach within the period of limitation "); Welter v. City of Milwaukee, 571 N.W.2d 459, 465 (Wis. Ct. App. 1997) ("Receipt of a pension installment payment that is less than that required by contract is a separate breach of that contract. Accordingly, the [plaintiffs] have six years to sue on any pension installment that was less than it should have been." (citation omitted)); Lutz v. Chesapeake Appalachia, LLC, 717 F.3d 459, 468-70 (6th Cir. 2013) (surveying decisions); Restatement (Second) of Contracts § 243 cmt. c (1981) ("It is well established that if those duties of the party in breach at the time of the breach are simply to pay money in installments, not related to one another in some way, . . . then a breach as to any number less than the whole of such installments gives rise to a claim merely for damages for partial breach.").

court affirmed dismissal of a breach of contract action filed six years after the defendant breached the parties' agreement by incorrectly adjusting the interest rate to a higher rate. The appellate court's decision turned on its determination that there was never any breach, not that the claims were time-barred. *Id.* The court explained that the parties agreed to the higher interest rate "and that payments of the note at that rate did not constitute breaches of the agreement." *Id.* Although the court concluded its discussion by stating, "Accordingly, Messner Manor's claim for excessive interest rate is time barred," *id.*, the court's analysis focused solely on whether there was any breach at all, not on whether there was a breach within the limitations period. *Id.* at 158-60.

297. As the Wisconsin Court of Appeals later clarified, "Messnor Manor contains no meaningful discussion of the application of the contract statute of limitations to an arguably ongoing series of individual breaches relating to the same agreement." Jahn Transfer, 2012 Wisc. App. LEXIS 484, at *6. The court "admit[ted] that [its] opinion [in Messner Manor] states that the claim was time barred, but that statement is an obvious drafting error. Id. The court explained that Messner Manor "affirmed dismissal of the breach of contract claim on the basis that there was no breach," not that the claim was time barred. Id. at *5.

298. WARF's reliance on *Air Transport Association of American v. Lenkin*, 711 F. Supp. 25 (D.D.C. 1989) — a 27-year old district court opinion applying District of Columbia law — is likewise misplaced. As in *Messner Manor*, the district court dismissed a contract claim on the ground that was no breach. *Id.* at 29. The court alternatively held that the contract claim was time barred because the plaintiff's claims for "nonpayment of installments" were based on a dispute over the interpretation of the contract that predated the limitations period. *Id.* at 28. On appeal, the Court of Appeals affirmed *Air Transport* only on the basis that there was no breach,

and expressly declined to address the court's alternative holding regarding the statute of limitations. *Air Transp. Ass'n v. Lenkin*, 899 F.2d 1265, 1266 (D.C. Cir. 1990).

299. Like *Messner Mannor*, *Air Transport* has been criticized and distinguished in subsequent decisions. For example, in *Lakeview Management v. Care Realty, LLC*, No. 07-cv-303-SM, 2010 U.S. Dist. LEXIS 5069, at *9-10 (D.N.H. Jan. 22, 2010), the court refused to apply *Air Transport* because it conflicted with Wisconsin law. *See also Total Control, Inc. v. Danaher Corp.*, 359 F. Supp. 2d 387, 392 n.6 (E.D. Pa. 2005) (rejecting *Air Transport's* reasoning because "any contractual dispute that reaches court can be characterized alternatively as a simple breach of a contractual duty or as a matter of differing interpretation of what constitutes a party's duties under a contract"); *Artesian Water Co. v. Chester Water Auth.*, No. 2:10-cv-07453-JP, 2013 U.S. Dist. LEXIS 188908, at *46 (E.D. Pa. Oct. 16, 2013) ("Pennsylvania courts have repeatedly and specifically rejected [*Air Transport's*] holding.").

300. Here, the IIA's Annual Payment Provision required WARF to make periodic royalty payments to Washington University: "WARF will pay to [Washington University] its share of Net Revenue due under this Agreement every 12 months by August 31 for the preceding 12-month period beginning July 1 and ending June 30. (JX1 at § 5.) As WARF's damages expert acknowledged, the IIA required WARF to calculate the amounts to remit to Washington University by taking "the top line revenue from Abbott," "look[ing] at what relative value it has allocated to Washington University," and "us[ing] that as one of the inputs to the calculation." (Trial Tr. 1105:3-23 (Ms. Mulhern).) WARF breached the IIA each year it made annual royalty payments less than what was "due under this Agreement" to Washington University. Under Wisconsin's periodic payment rule, each annual underpayment gave rise to a new claim for breach of contract, triggering a new six-year statute of limitations period on each claim.

301. Washington University may therefore pursue any breach of contract claims based on any improper annual underpayments that WARF made on or after April 9, 2007 — the date of the Standstill Agreement. (*See* Proposed FOF ¶ 173.) WARF's first annual underpayment after that date occurred on August 21, 2007, covering the royalty period from July 1, 2006 to June 30, 2007. (*See* JX30.) Therefore, under Wisconsin's periodic payment rule, Washington University may assert breach of contract claims based on WARF's underpayments on and after April 9, 2007, which cover underpaid royalties dating back to July 1, 2006.

302. Damages under Wisconsin's periodic payment rule are as follows:

RV%	Damages Scenario	Periodic Payment (July 1, 2006)	Prejudgment Interest	Total
33%	Treat '497, '925, '815 equally	\$ 26,202,710	\$ 9,329,268	\$ 35,531,978
30%	'815 is only Ancillary Patent with substantial value	\$ 23,502,106	\$ 8,368,355	\$ 31,870,461
29%	Treat '815 same as WARF treated multiple sclerosis ancillary patent	\$ 22,691,925	\$ 8,080,081	\$ 30,772,006
27.1%	Allocate 4% to 4 Ancillary Patents that potentially relate to making paricalcitol	\$ 21,125,575	\$ 7,522,752	\$ 28,648,326

303. Although Washington University has found no case under Wisconsin law that would require cutting off damages beginning on April 9, 2007, Washington University has nevertheless prepared an alternative damages calculation with a damages start date of April 9, 2007. But because the Standstill Agreement tolled all periods of limitation, repose, and laches "relating to *any claim* concerning the IIA or the '815 patent" (*see* JX199 at 1 (emphasis added)),

the parties' agreement allowed it to pursue *any claims* that existed as of April 9, 2007, including all resulting injury associated with those claims. *See also Segall v. Hurwitz*, 339 N.W.2d 333, 343 (Wis. Ct. App. 1983) ("The injured party may assert a claim for damages from the date of the first breach within the period of limitation."), *superseded on other grounds by Turner v. Sanoski*, 787 N.W.2d 429 (Wis. Ct. App. 2010). Construing the parties' agreement as barring all *damages* before April 9, 2007 would not implement the parties' intent, as reflected in the agreement's plain language, and would result in the anomalous result whereby Washington University preserved its ability to sue for all annual breaches that accrued on or after April 9, 2007, but could not seek redress for all the injury caused by those breaches. ¹²

¹² In the event the Court disagrees with Washington University's analysis on this issue, Washington University's damages beginning on a start date of April 9, 2007 are as follows:

RV%	Damages Scenario	Periodic Payment (April 9, 2007)	Prejudgment Interest	Total
33%	Treat '497, '925, '815 equally	\$ 24,134,218	\$ 8,236,266	\$ 32,370,484
30%	'815 is only Ancillary Patent with substantial value	\$ 21,646,472	\$ 7,387,829	\$ 29,034,301
29%	Treat '815 same as WARF treated multiple sclerosis ancillary patent	\$ 20,900,149	\$ 7 ,133,297	\$ 28,033,446
27.1%	Allocate 4% to 4 Ancillary Patents that potentially relate to making paricalcitol	\$ 19,457,256	\$ 6,641,203	\$ 26,098,460

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- b. Washington University May Also Recover Damages
 Dating Back to July 1, 2006 or, Alternatively, to
 October 14, 2008 Based on WARF's Duty to Revalue
- 304. Washington University may also assert claims for breach of the implied covenant of good faith and fair dealing dating back to July 1, 2006 or, alternatively, to October 14, 2008 based on WARF's duty to revalue the '815 patent to fairly compensate Washington University for the royalties that WARF received from licensing the '815 patent to Abbott.
- 305. This theory derives from the Third Circuit's reversal of the Court's grant of summary judgment in WARF's favor on its statute of limitations defense. *See Wash. Univ.*, 703 F. App'x at 109. The Third Circuit did not address Washington University's argument on appeal that Wisconsin's periodic payment rule allowed Washington University to assert contract claims based on each annual underpayment regardless of any ongoing duty to revalue independent of the Annual Payment Provision. Instead, the Third Circuit addressed Washington University's argument "that the implied covenant of good faith and fair dealing creates an inherent duty in WARF to reassign a value to the Patent, and WARF's failure to do so makes WARF liable for breach of contract." *Id.* The Third Circuit held that "an issue of fact remains as to whether WARF had a continuing obligation to reassign a value to the '815 patent' sufficient to warrant reversal of the Court's summary judgment ruling. *Id.*
- 306. Based on the Third Circuit's decision, WARF has incorrectly argued that Washington University *cannot* invoke Wisconsin's periodic payment rule unless it first establishes a duty to revalue under the implied covenant of good faith and fair dealing. WARF's position is based on a misreading of Wisconsin law. As discussed above, Wisconsin law applies the periodic payment rule as a matter of law to contracts that call for periodic payments, as the IIA does here. WARF has not cited a single case under Wisconsin law that has required proof of an independent continuing duty, other than a periodic payment obligation, before applying

Wisconsin's periodic payment rule.

307. WARF's position also misconstrues the scope of the Third Circuit's mandate. The Third Circuit's opinion and mandate contained no limitation on the scope of the remand proceedings. The Third Circuit merely "reversed" this Court's prior summary judgment ruling without stating that it was remanding "for further proceedings consistent with" its opinion or for resolution of a narrow subset of facts. To the contrary, the Third Circuit clarified that its identification of specific factual disputes in its opinion was "not intended as an exhaustive listing of the issues of material fact" and that it identified those issues "merely to illustrate that this record does not support summary judgment, and WARF was therefore not entitled to judgment as a matter of law." Wash. Univ., 703 F. App'x at 110 n.22. The Court's resolution of this case, therefore, does not depend on any purported "subset" of factual issues. Further, even in a situation where the Third Circuit remands "for further proceedings consistent with this opinion," the mandate rule in that situation allows a district court upon remand to "consider, as a matter of first impression, those issues not expressly or implicitly disposed of by the appellate decision." Bankers Tr. Co. v. Bethlehem Steel Corp., 761 F.2d 943, 949-50 (3d Cir. 1985). Thus, a trial court on remand is "free to make any order or direction in further progress of the case, not inconsistent with the decision of the appellate court, as to any question not settled by the decision." Id. at 950. Here, because the Third Circuit did not address Washington University's argument that Wisconsin's periodic payment rule applied independent of any ongoing duty to revalue, the Court is "free to make any order" on remand on that issue. See id.

308. In any event, Washington University *did* establish that WARF had a duty to revalue under the implied covenant of good faith and fair dealing, rendering WARF's arguments about the scope of the mandate moot. As WARF's tech transfer expert, Dr. Severson, admitted,

WARF had a duty to revisit its value allocations under the IIA in the face of an appropriate challenge by Washington University. (Trial Tr. 1028:22-1029:3 (Dr. Severson); *see also* Trial Tr. 327:10-328:15 (Dr. Cleare).) Of course, a condition precedent to WARF's duty to revalue in that situation is that Washington University actually bring a challenge. But in this case, WARF's conduct prevented Washington University from learning information that Washington University needed to make an appropriate challenge. (*See infra* ¶ 66-95, 107-113, 127-137.) Washington University's failure to challenge each annual underpayment within the six-year statute of limitations period is therefore excused under the prevention doctrine.

- that essentially prohibits a contracting party from capitalizing on the non-occurrence of a condition that the party prevented from occurring. *See NLRB v. Local 554, Graphic Commc'ns Int'l Union*, 991 F.2d 1302, 1307 (7th Cir. 1993) ("The nonoccurrence or nonperformance of a condition is excused where that failure of the condition is caused by the party against whom the condition operates to impose a duty."); *W & G Seaford Assocs., L.P. v. E. Shore Mkts., Inc.*, 714 F. Supp. 1336, 1341 (D. Del. 1989) ("A cardinal principle of contract law regarding conditions is that, 'where a party's breach by non-performance contributes materially to the non-occurrence of a condition of one of his duties, the non-occurrence is excused.""); Restatement (Second) of Contracts § 245 cmt. a (1981) ("Where a duty of one party is subject to the occurrence of a condition, the additional duty of good faith and fair dealing imposed on him under § 205 may require some cooperation on his part, either by refraining from conduct that will prevent or hinder the occurrence of that condition or by taking affirmative steps to cause its occurrence.").
- 310. Here, if WARF had not concealed information that Washington University needed to determine if it had a valid claim (*see* Proposed FOF ¶¶ 66-95, 107-113, 127-137),

Washington University could have challenged WARF's relative valuation, triggering WARF's duty to revalue. Because WARF's conduct prevented — and thereby excused — Washington University from actually tendering such a challenge, WARF had an ongoing duty to revalue each year it made annual payments to Washington University based on its improperly low relative valuation.

311. Damages under this scenario are the same as those stated above in Paragraph 302 because WARF's ongoing duty to revalue allows Washington University to assert all claims for breach within the six-year limitations period. Again, damages under this scenario are as follows:

RV%	Damages Scenario	Periodic Payment (July 1, 2006)	Prejudgment Interest	Total
33%	Treat '497, '925, '815 equally	\$ 26,202,710	\$ 9,329,268	\$ 35,531,978
30%	'815 is only Ancillary Patent with substantial value	\$ 23,502,106	\$ 8,368,355	\$ 31,870,461
29%	Treat '815 same as WARF treated multiple sclerosis ancillary patent	\$ 22,691,925	\$ 8,080,081	\$ 30,772,006
27.1%	Allocate 4% to 4 Ancillary Patents that potentially relate to making paricalcitol	\$ 21,125,575	\$ 7,522,752	\$ 28,648,326

312. At trial, the Court inquired into a damages calculation based on the date of Mr. Stoveken's October 14, 2008 email. (Trial Tr. 1148:17-1149:21.) In that email, Mr. Stoveken told WARF's Director of Licensing that the '815 patent covered "exactly the application and population for which Abbott targets and sells Zemplar for" because "SHPT = renal osteodystrophy." (JX50 at 1.) A damages calculation with a start date based on Mr. Stoveken's

email would be appropriate if at least the following conditions are met: (1) equitable estoppel does not bar WARF's statute of limitations defense, (2) Wisconsin's periodic payment doctrine requires the Court to find an independent duty to revalue under the implied covenant, despite cases like *Noonan*, *Jahn Transfer*, *Policeman's Annuity*, *Jensen*, and *Maryland Staffing*, (3) WARF did not conceal information that Washington University needed to bring a challenge to WARF's undervaluation, giving rise to a duty to revalue with each annual underpayment, and (4) WARF assigned negligible 0.968% value to the '815 patent in October 1998 based on a mistaken belief that the '815 patent (relating to a treatment for RO) did not cover Zemplar's approved use (relating to a treatment for SHPT), and (5) WARF first learned of its mistake when Mr. Stoveken realized that "SHPT = renal osteodystrophy" in 2008.

- 313. There are a number of reasons why the evidence does not support factual and legal findings on each of those prerequisites. Equitable estoppel *does* apply here. (*See supra* ¶¶ 264-289.) Wisconsin's periodic payment doctrine does *not* require an independent duty to revalue. (*See supra* ¶¶ 293-301.) Abbott knew as of April 1998 that physicians would prescribe Zemplar to treat RO because of the equivalence of SHPT and RO. (*See* Proposed FOF ¶ 77.) WARF knew as of June 12, 1998 that the '815 patent "directly supports" Zemplar. (*See id.*) Therefore, Mr. Stoveken, who joined WARF in 2007, was *not* the first WARF employee to realize that the '815 patent covered "exactly the application and population for which Abbott targets and sells Zemplar for" because "SHPT = renal osteodystrophy." (JX50 at 1.)
- 314. Nevertheless, and in the alternative, Washington University asked WARF's tech transfer expert, Dr. Severson, whether WARF would have a duty to revalue in a hypothetical scenario "where WARF assigns a relative value to the '815 patent based on its belief that the '815 patent doesn't read on the FDA approved indication, but then later learns that that was

mistaken, [and] that the '815 patent does read on the approved indication." (Trial Tr. 1028:4-17 (Dr. Severson).) In that situation, Dr. Severson agreed that WARF "had a duty to revalue." (*Id.*)

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RV%	Damages Scenario	Stoveken Email (Oct. 14, 2008)	Prejudgment Interest	Total
33%	Treat '497, '925, '815 equally	\$ 18,902,086	\$ 5,755,882	\$ 24,657,967
30%	'815 is only Ancillary Patent with substantial value	\$ 16,952,363	\$ 5,162,503	\$ 22,114,866
29%	Treat '815 same as WARF treated multiple sclerosis ancillary patent	\$ 16,367,446	\$ 4,984,490	\$ 21,351,936
27.1%	Allocate 4% to 4 Ancillary Patents that potentially relate to making paricalcitol	\$ 15,236,607	\$ 4,640,330	\$ 19,876,937

C. WARF'S Laches Defense Fails

- 316. WARF's laches defense suffers from the same critical defects as its statute of limitations defense. WARF's pattern of deception and concealment regarding the '815 patent and WARF's valuation of it precludes WARF from asserting a laches defense.
- 317. The lynchpin of a laches defense is that the plaintiff must "know the facts and take no action." *Policemen's Annuity*, 630 N.W.2d at 244. The essential elements of a laches defense are: "(1) Unreasonable delay in commencing the action; (2) knowledge of the course of events and acquiescence therein; and (3) prejudice to the party asserting the defense." *Paterson v. Paterson*, 242 N.W.2d 907, 909 (Wis. 1976). A litigant who files suit within the statute of

limitations period "cannot be said to be 'unduly slumbering' on his rights." *See Schroeder v. Goth*, No. 03-C-0299-C, 2004 U.S. Dist. LEXIS 7649, at *15 (W.D. Wis. Apr. 28, 2004). In addition, the plaintiff's unreasonable delay must cause *evidentiary prejudice* resulting in the defendant's inability to defend itself on the merits. *See State ex rel. Coleman v. McCaughtry*, 714 N.W.2d 900, 907 n.10 (Wis. 2006). Prejudice cannot be presumed from delay alone. *Id.* WARF bears the burden of proof on all three elements. *See id.* at 910-11.

- 318. WARF cannot meet its burden of proof on any element of its laches defense, let alone on all three. First, WARF cannot show that Washington University "unreasonabl[y] delay[ed]" in bringing suit. Paterson, 242 N.W.2d at 909. Washington University received the Hospira subpoena that triggered the cascade of events leading to this lawsuit in September 2012. (See Proposed FOF ¶ 166.) As soon as Washington University learned that WARF and Abbott had asserted the '815 patent in litigation to block Hospira's attempt to sell a generic version of Zemplar, Washington University immediately launched an investigation, engaged outside counsel, and within three months pressed its concerns to WARF that its 0.968% relative valuation did not appear consistent with its assertion of the '815 patent against Hospira. (See id. ¶¶ 166-174.) Washington University and WARF then entered into a Standstill Agreement on April 9, 2013 (JX199), and after negotiations broke down, Washington University filed suit on December 26, 2013. (JX337.) Washington University did not delay in asserting its rights, but promptly raised them after learning information in September 2012 that suggested WARF had undervalued the '815 patent and concealed the information needed to assess its true relative value.
- 319. Second, WARF cannot establish that Washington University "[knew] of the course of events and acquiescence[d] therein" based on events that took place before 2012.

Paterson, 242 N.W.2d at 909. Before receiving Hospira's subpoena alerting it to WARF's assertion of the '815 patent in litigation to block generic competition for Zemplar, WARF had consistently represented to Washington University that the '815 patent was "ancillary" and worth a negligible "0.968%" as compared to WARF's solely-owned patents in the 1998 Abbott License. (Proposed FOF ¶ 66-95, 107-113, 127-137.) WARF's own tech transfer expert admitted that by withholding the 1998 Abbott License from Washington University, which WARF did under a false assertion that the license contained "confidentiality provisions" that prevented its disclosure, Washington University "couldn't determine or evaluate whether WARF had assigned a fair relative value to the '815 patent in proportion to the other patents in the portfolio. (Trial Tr. 989:12-22 (Dr. Severson).) He further admitted that Washington University had "no reason at this time to think WARF wasn't being straightforward with them." (Trial Tr. 990:6-10 (Dr. Severson).)

320. As Washington University showed, WARF systematically deprived Washington University of the information in WARF's possession bearing on the '815 patent's substantial contributions to the development and commercialization of Zemplar (*see* Proposed FOF ¶ 66-95, 107-113, 127-137), which contradicted WARF's representations that the patent was "ancillary" and held negligible value as compared to WARF's solely-owned patents in the Abbott portfolio. (*See id.* ¶ 127-137.) Washington University also showed that WARF made numerous, highly material misrepresentations about the circumstances in which it had assigned relative value to the '815 patent, including misrepresenting that WARF had a "policy" and "regular practices" of *not* assigning substantial value to method of treatment patents, like the '815 patent, while concealing that WARF had a policy and practice of doing the exact opposite. (*See id.*) Because of WARF's multiple modes of concealment and misrepresentation,

Washington University did not "know the facts" until it learned of WARF's misconduct in this lawsuit. (*See id.*)

321. Finally, WARF failed to establish any actual prejudice to WARF's ability to defense against Washington University's claims. WARF's argument that it suffered "economic prejudice" because it allegedly overpaid royalties to inventors at University of Madison-Wisconsin based on WARF's self-dealing relative valuation does not constitute the kind of evidentiary prejudice required to state a laches defense under Wisconsin law. See Coleman, 714 N.W.2d at 909-10 (litigant must show actual prejudice relating to ability to defend case).

D. WARF'S Accord and Satisfaction Defense Fails

- 322. WARF waived its accord and satisfaction defense by failing to timely disclose it during discovery. ¹³ *See* Fed. R. Civ. P. 37. Alternatively, the defense fails on the merits.
- 323. An accord and satisfaction is an agreement between the parties to discharge an existing disputed claim, and therefore requires an offer, acceptance, and consideration. *See*

¹³ Because WARF filed a motion to dismiss in early 2014 (D.I. 14), which the Court took under submission and disposed of as moot at the summary judgment stage (D.I. 130), WARF did not file an Answer identifying its affirmative defenses until more than two years after the March 16, 2015 fact discovery cutoff. (D.I. 145.) To elicit WARF's affirmative defenses during discovery, Washington University served a contention interrogatory asking WARF to describe in detail all affirmative defenses it intended to assert in its pleadings. WARF's response did not disclose an accord and satisfaction defense. Shortly after the close of expert discovery, Washington University's counsel offered to enter into a stipulation with WARF to allow WARF to file an Answer and disclose its affirmative defenses without prejudice to its pending motion to dismiss. Washington University warned WARF that it would ask the Court to find that WARF waived any affirmative defenses not timely disclosed to Washington University. WARF refused Washington University's request and failed to disclose an accord and satisfaction defense. Two months before the scheduled February 2016 trial (and also nine months after the fact discovery cutoff and six months after the expert discovery cutoff), WARF disclosed for the first time that it would seek to introduce an accord and satisfaction defense at trial. WARF's untimely disclosure prejudiced Washington University's ability to develop a factual record on this issue through fact and expert depositions. It also prevented Washington University from challenging the defense on summary judgment. In light of WARF's untimely disclosure of its accord and satisfaction defense and its resulting evidentiary prejudice to Washington University, WARF should be precluded from asserting it now.

Hoffman v. Ralston Purina Co., 273 N.W. 214, 217 (Wis. 1979). The standard situation is when "a debtor offers a check to its creditor as full payment for a claim, and the creditor cashes that check," in which event the law "treat[s] the creditor as having accepted the debtor's offer to settle the debt for the amount of the check." See Schuetta v. Aurora Nat'l Life Assurance Co., 27 F. Supp. 3d 949, 955 (E.D. Wis. 2014) (applying Wisconsin law). To establish an accord and satisfaction, WARF must show (1) that it offered to pay Washington University "something of monetary value" on the condition that Washington University accept it as "full satisfaction of [its] [contract] claim[s]," and (2) that Washington University accepted the offer and discharged WARF's liability on those claims. See id. (citation omitted).

- 324. WARF cannot meet this standard. Because of WARF's misleading statements, Washington University was unaware that WARF was regularly underpaying royalties for years. WARF never provided Washington University with notice that it intended its historical royalty checks to be in full satisfaction of a known and disputed claim. After the parties' dispute arose in 2012, WARF never tendered its checks to Washington University in "full satisfaction" of its liability on Washington University's claims. Nor did Washington University accept any checks from WARF for the purpose of discharging WARF's liability. To the contrary, after Washington University approached WARF about a potential dispute over WARF's relative valuation, the parties entered into a Standstill Agreement, effective April 9, 2013, in which they agreed that Washington University's claims would be preserved against the running of any applicable statute of limitations, (JX199 at 1), which reflected a mutual intent to *preserve* Washington University's claims, not discharge them.
- 325. WARF therefore cannot demonstrate that Washington University accepted any checks from WARF in "full satisfaction" of a known and disputed claim. The Court should

therefore also reject WARF's accord and satisfaction defense on the merits.

IV. CONCLUSION

326. Based on WARF's breaches of the IIA, its fraudulent misconduct, and its grossly deficient valuation of the '815 patent, Washington University asks that WARF be equitably estopped from asserting the statute of limitations as a defense to Washington University's claims, and that the Court enter judgment in Washington University's favor in the amount of \$39,208,887 representing damages under a 33% fair relative valuation, plus prejudgment interest in the amount of \$18,444,216 representing 5% simple interest at the Wisconsin statutory rate, for a total of \$57,653,103.

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